

NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

August 2016

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: 08/09/2016

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									
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	emangioma	(6				(00)		
		1/50 (2%)	••	05.00/		1/50 (2%)		05 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)		25. 22/		1/50 (2%)		25
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Leukemia: Granulocytic								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:	. Monocytic. Mo	nonuclear, or Undiffere	entiated					
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	0/50 (0%) 0/50 (0%)			Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign,	Total Malignant, NOS Total	0/50 (0%) 0/50 (0%) 1/50 (2%)	Mean 2%		Total Total	` '	Mean 0% Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign,	Total Malignant, NOS Total	0/50 (0%) 0/50 (0%) 1/50 (2%)	Mean 2%			0/50 (0%)		
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Malignar	Total Malignant, NOS Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Total Malignant, NOS Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 2%			0/50 (0%) 0/50 (0%) 0/50 (0%)		
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Malignar	Total Malignant, NOS Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

> Route: GAVAGE Vehicle: CORN OIL

Contract/Lab: All Laboratories

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

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		Male				Female							
*Adrenal Medulla: Pheochromocytoma Benign 5/50 (10%) 0/50 (0%)													
	5/50 (10%)				0/50 (0%)								
Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%						
	1/50 (2%)				0/50 (0%)								
Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%						
ignant	2/50 (4%)				0/50 (0%)								
Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%						
nign, Complex,	Malignant, NOS 8/50 (16%)			Total	0/50 (0%)	M 00/	CD 00/						
	` '				, ,		SD 0%						
	0/50 (00/)				0/50 (00/)								
Total	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%						
nign	0/50 (0%)				4/50 (20/)								
	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%							
	Total nplex Total ignant Total nign, Complex,	5/50 (10%) Total 5/50 (10%) nplex 1/50 (2%) Total 1/50 (2%) ignant 2/50 (4%) Total 2/50 (4%) nign, Complex, Malignant, NOS 8/50 (16%) Total 8/50 (16%) Total 0/50 (0%) Total 0/50 (0%)	Total 5/50 (10%) Mean 10%	Society	Total 5/50 (10%) Mean 10% SD 0% Total	1/50 10%	Sign Sign						

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 08/09/2016

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: CORN OIL

			Male				Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Brain: 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%				
*Epididymis: Sarcoma		0/50 (0%)										
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%								
#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%				
*Heart: Schwannoma Malignant		` '										
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Large: Colon/Rect Leiomyoma		0/50 (00/)				0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

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

			Male				Female	
		(0%)				0/50 (0%)		
	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		(0%)				0/50 (0%)		
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	2/50	(4%)				0/50 (0%)		
Total	2/50 (4%)	(470)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50	(0%)				0/50 (0%)		
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		(4%)				0/50 (0%)		
	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	4/50	(00/)				0/50 (00)		
Total		(2%)	Moan 20/	SD 0%	Total	, ,	Moon 0%	SD 0%
		Total 0/50 (0%) ecified: 0/50 Total 0/50 (0%) 2/50 Total 2/50 (4%) 0/50 Total 0/50 (0%) Total 2/50 Total 2/50 2/50 (4%)	Total 0/50 (0%) ecified: 0/50 (0%) Total 0/50 (0%) 2/50 (4%) Total 2/50 (4%) Total 0/50 (0%) Total 0/50 (0%) Total 2/50 (4%) Total 2/50 (4%) 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0% ecified: 0/50 (0%) Total 0/50 (0%) Mean 0% 2/50 (4%) Total 2/50 (4%) Mean 4% 0/50 (0%) Mean 0% 1/50 (4%) Mean 0% 1/50 (2%)	O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Pacified: O/50 (0%) Total O/50 (0%) Mean 0% SD 0% SD 0% Total O/50 (0%) Mean 4% SD 0% Total O/50 (0%) Mean 4% SD 0% Total O/50 (0%) Total O/50 (0%) Mean 4% SD 0% Total O/50 (0%) Mean 4% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total ecified: O/50 (0%)	O/50 (0%) Mean 0% SD 0% Total O/50 (0%) O/	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% **Scified:** 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% Total 2/50 (4%) Mean 4% SD 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% 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% **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%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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	
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	V	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma	a								
•		1/50	(2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	V	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinon	na or Hepatocell		(2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinon		lar Adenoma, or ∣					2/50 (4%)		
			` '				` '		
Overall Incidence	Total	1/50 (2%)	, , ,	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
Overall Incidence *Lung: Alveolar/Bronchiolar Ad		1/50 (2%)	Λ				2/50 (4%)		SD 0%
*Lung: Alveolar/Bronchiolar Ad	lenoma	1/50 (2%) 0/49	(0%)				2/50 (4%) 1/50 (2%)		
*Lung:		1/50 (2%)	(0%)				2/50 (4%)		SD 0% SD 0%
*Lung: Alveolar/Bronchiolar Ad	lenoma Total	0/49 0/49 (0%)	(0%)				2/50 (4%) 1/50 (2%)		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

				Male				Female	
*Lung: Sarcoma									
Overall Incidence	Total	0/49 (0%)	0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma									
Overall Incidence	Total	1/50 (1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (0%)				3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	0 76)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Carcinoma	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				iviean 0%	30 0%	i Otai		iviean 6%	30 0%
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		1/50 (2%)				29/50 (58%)		
Overall Incidence	Total	1/50 (2%)	Z /0)	Mean 2%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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: 08/09/2016

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			Male				Female					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma 1/50 (2%) Overall Incidence Total 1/50 (2%) Mean 2% SD 0% Total 30/50 (60%) Mean 60% SD 0%												
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, or					20/50 (040/)						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%				
#Mammary Gland: Myoepithelioma		0/50 /00/\				4/50 (20/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Oral Cavity (Oral Mucosa Squamous Cell Carcinor	, Tongue, Phary	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 Mucosa Squamous Cell Carcinor	, Tongue, Phary	nx, Tooth, Gingiva):				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Mucosa: Squamous Cell Carcinor	ma	1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/09/2016

Route: GAVAGE Vehicle: CORN OIL

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

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Granulosa-Theca Tumor Benign** 1/50 (2%)Overall Incidence Total 1/50 (2%) Mean 2% SD 0% *Ovary: Thecoma Benign 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) *Ovary: **Tubulostromal Carcinoma** 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% *Pancreas: Adenoma 5/50 (10%)0/50 (0%)**Overall Incidence** Total 5/50 (10%) Mean 10% SD 0% Total Mean 0% SD 0% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 08/09/2016

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Pancreas: Carcinoma or 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%
						0/30 (0/0)		
*Pituitary Gland: Pars Distal Adenoma	lis or Unspeci	fied Site:						
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		fied Site:						
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Salivary Glands: Schwannoma Malignant		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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%
#Skeletal Muscle: 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%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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			Total 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0%				
#Skin: Basal Cell Carcinoma										
		1/50 (2%)				` '				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or N	OS)							
Dubui Ocii Odi Oillollia C	n Busosquamou	1/50 (2%)	00,			0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%		` ,		SD 0%		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tur 1/50 (2%)	mor (benign, maligna	ant or		0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal or Sq. Cell Carcii	noma, Carcinoma	a, Basosq. Tumor (M or Bratoacanthoma, Trichoep 6/50 (12%) 6/50 (12%)	3), Basal Cell Adeno		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma										
		5/50 (10%)		05.00/		1/50 (2%)	••	00.00		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Skin: Fibroma, Fibrosarcoma	ı, Sarcoma, Myxo	oma, Myxosarcoma, or F	ibrous Histiocytoma							
		7/50 (14%)		25. 22/		2/50 (4%)	••	05.00/		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male				Female	
#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%
#Skin: Fibrosarcoma, Sarcoma,								
i ibi osai coma, sai coma,	wyxosarcoma	2/50 (4%)	illa			1/50 (2%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: 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	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%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 08/09/2016

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#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%
								00 070
#Skin: Neurofibrosarcoma or ScI	hwannoma (m	•				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: Neurofibrosarcoma, Neuro	ofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Schwannoma Malignant		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Carcinom	a	4/50 (00/)				0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoms or Carcinoma	a, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t or NOS),				
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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

Route: GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: CORN OIL

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			Male				Female					
#Skin: Squamous Cell Papilloma 1/50 (2%) 0/50 (0%)												
		` '				` '						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin:												
Squamous Cell Papilloma	or Papilloma	1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma, Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma,	Papilloma, o	r Keratoacanthoma 5/50 (10%)			T-1-1	0/50 (0%)	M 00/	OD 00/				
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%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma	•••••											
• " "	.	0/50 (0%)		00.00/	-	0/50 (0%)		00.00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female					
#Stomach, Forestomach: Squamous Cell Carcinoma 1/50 (2%) 1/50 (2%)												
		1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#Stomach, Forestomach: Squamous Cell Carcinoma												
		1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Testes: Adenoma		3/49 (6%)										
Overall Incidence	Total	3/49 (6.12%)	Mean 6.12%	SD 0%								
*Thymus: Thymoma Benign		1/46 (2%)				0/47 (0%)						
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma: 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		10/10 (05-1)										
Occupation of the second	T-1-1	13/50 (26%)	M 000/	OD 00/	T-1-1	11/49 (22%)	Mara 00 4501	00, 00/				
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22.45%)	Mean 22.45%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 08/09/2016

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: GAVAGE Vehicle: CORN OIL

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

			Male				Female	
*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		40/50 (000)				44/40 (000/)		
Overall Incidence	Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22%) 11/49 (22.45%)	Mean 22.45%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal								
i oiyp otromai						10/50 (20%)		
Overall Incidence					Total	10/50 (20%)	Mean 20%	SD 0%
#Uterus: Sarcoma Stromal								
						2/50 (4%)		
Overall Incidence					Total	2/50 (4%)	Mean 4%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% 0/50 (0%) otal 0/50 (0%) Mean 0% SD 0%			
#Uterus: Sarcoma Stromal or Polyp	o Stromal								
Overall Incidence					Total	12/50 (24%)			
#Uterus: Squamous Cell Carcinom	a								
Overall Incidence					Total	(,	Mean 0%	SD 0%	
#Vagina: Granular Cell Tumor Beni	gn					0/50 (00/)			
Overall Incidence					Total	` '	Mean 0%	SD 0%	
#Vagina: Polyp						4/50 /29/)			
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Vagina: Schwannoma Malignant									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Zymbal's Gland: Carcinoma		0/50 (09/)				0/50 /00/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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			
#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%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 08/09/2016

Study Summary

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

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors						39/50 (78%) Total 39/50 (78%) Mean 78% SE 11/50 (22%) Total 11/50 (22%) Mean 22% SE 41/50 (82%) Total 41/50 (82%) Mean 82% SE 0/50 (0%) Total 0/50 (0%) Mean 0% SE		
-		30/50 (60%)				39/50 (78%)		
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%		` '		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 Tum	ors	37/50 (74%)				41/50 (82%)		
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	` ,	Mean 82%	SD 0%
#All Organs: Hemangioma		1/50 (2%)				` '		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		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 Hemangiosarcoma	angioma	4/50 (00)				0/50 /00/		
Overall Incidence	Total	1/50 (2%)	Maan 20/	CD 00/	Total	0/50 (0%)	Maan Ol/	CD 00/
	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
		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: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo	ononuclear, or Undifferent 3/50 (6%) 3/50 (6%)	ntiated Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,						05 070
#All Organs: Mesothelioma: Benign, Ma	lignant, 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%
#All Organs: Mesothelioma: Malignant								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
	Total	3/50 (6%) 3/50 (6%)		SD 0%		0/50 (0%)		
Overall Incidence			Mean 6%		Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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12/50 (24%) 12/50 (24%) 0/50 (0%) 0/50 (0%)	Mean 24%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
12/50 (24%) 0/50 (0%)				0/49 (0%)	Mean 0%	SD 0%
0/50 (0%)				, ,	Mean 0%	SD 0%
0/50 (0%)						·
` '						
0/50 (0%)				0/49 (0%)		
	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
2/50 (4%)				0/49 (0%)		
2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
lex, Malignant, NOS 14/50 (28%)				0/49 (0%)		
14/50 (28%)	Mean 28%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
2/50 (4%)				1/50 (2%)		
2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
0/50 /00/				0/50 (09/)		
` '	Moon 09/	SD 00/	Total	` '	Moon 00/	SD 0%
	14/50 (28%) 14/50 (28%) 2/50 (4%)	14/50 (28%) 14/50 (28%) Mean 28% 2/50 (4%) 2/50 (4%) Mean 4%	14/50 (28%) 14/50 (28%) Mean 28% SD 0% 2/50 (4%) 2/50 (4%) Mean 4% SD 0%	14/50 (28%) 14/50 (28%) Mean 28% SD 0% Total 2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total	14/50 (28%) 14/50 (28%) Mean 28% SD 0% Total 0/49 (0%) 7/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) 7/50 (2%) 0/50 (0%) 0/50 (0%)	14/50 (28%) Mean 28% SD 0% Total 0/49 (0%) Mean 0% 2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) 1/50 (2%) Mean 2% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 08/09/2016

Contract/Lab: All Laboratories

es

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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

			Male				Female				
*Brain: Oligodendroglioma, Gliom	a, or Astrocy										
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: Schwannoma Malignant	•••••	0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Epididymis: Sarcoma		4/50 (00/)									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%							
#Eye: Leiomyoma		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Heart: 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%			
#Intestine Large: Colon/Rect Leiomyoma											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Jejunum: Leiomyosarcoma								
-		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								
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%
*Islets, Pancreatic: Carcinoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		8/50 (16%)				2/50 (4%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Kidney: 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%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Harlan Sprague-Dawle

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Liver: Hepatocellular Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinoma Overall Incidence	or Hepatocel	lular Adenoma 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
				·······································		10tai	2/30 (4/0)		
*Liver: Hepatocellular Carcinoma,	Hepatocellu	lar Adenoma, or 0/50	Hepatob	lastoma			2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Aden	oma								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Carci	noma or Alve	eolar/Bronchiola	ır Adenon	na			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(=,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Lung: Sarcoma		0/50 /09/	<u> </u>			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%
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (0%				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (0%)			4/50 (8%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
#Mammary Gland: Carcinoma	-	0/50 (0%	,	OD 004	-	5/50 (10%)		00.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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 (4%				20/50 (40%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Fibroma, Fibroadenom	na or Adenoma							
•		2/50 (4%)				23/50 (46%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%
#Mammary Gland: Fibroma, Fibroadenon								
		2/50 (4%)				27/50 (54%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	27/50 (54%)	Mean 54%	SD 0%
#Mammary Gland: Myoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Muses		nx, Tooth, Gingiva):						
• •		quamous, or Papilloma				0/50 (0%)		
• •		quamous, or Papilloma 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Carcin	oma, Papilloma Ś	0/50 (0%)		SD 0%	Total	` '	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Ovary: Granulosa Cell Tumor Beni	gn							
Overall Incidence					Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor: Ben	ign, Maligna	nt, NOS						
Overall Incidence					Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa-Theca Tumor Be	enign							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign						(20)		
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%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma								
		11/50 (22%)				18/50 (36%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Distali Carcinoma or Adenoma						18/50 (36%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 (00)				0/50 (00)		
Occupation of James	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female			
#Skin: Basal Cell Carcinoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin:		s Tumor (malignant or N							
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		ma, Basosquamous Tu	mor (benign, maligna	ant or		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,	noma, Carcinoma Sq Papilloma, Ker Total	a, Basosq. Tumor (M or atoacanthoma, Trichoe 4/50 (8%) 4/50 (8%)	B), Basal Cell Adeno pithelioma Mean 8%	ma, SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
Basal or Sq. Cell Carci	Sq Papilloma, Ker	atoacanthoma, Trichoe 4/50 (8%) 4/50 (8%)	pithelioma		Total	1/50 (2%)	Mean 2%	SD 0%	
Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin: Fibroma	Sq Papilloma, Ker	atoacanthoma, Trichoe 4/50 (8%)	pithelioma		Total 		Mean 2% Mean 0%	SD 0%	
Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin: Fibroma Overall Incidence	Sq Papilloma, Ker Total Total	atoacanthoma, Trichoe 4/50 (8%) 4/50 (8%) 0/50 (0%) 0/50 (0%)	Mean 8% Mean 0%	SD 0% SD 0%	Total	1/50 (2%) 0/50 (0%) 0/50 (0%)			
Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin: Fibroma Overall Incidence	Sq Papilloma, Ker Total Total	atoacanthoma, Trichoe 4/50 (8%) 4/50 (8%) 0/50 (0%)	Mean 8% Mean 0%	SD 0% SD 0%	Total	1/50 (2%) 0/50 (0%) 0/50 (0%)			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%	<i>'</i>			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,								
		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: 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		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: 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 /69/	```			0/50 (09/)		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)) Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female			
#Skin: Lipoma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Neurofibrosarcoma or	Schwannoma (m	alignant or NOS)							
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Neurofibrosarcoma, Ne	eurofibroma, or S	chwannoma (benign, ma	alignant or NOS)						
		0/50 (0%)	,			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Schwannoma Malignar	nt								
•		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 Carcine	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%	
#Skin:									
_	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	at or NOS),					
		0/50 (0%)				1/50 (2%)			
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male			Female			
#Skin: Squamous Cell Papilloma										
		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma	or Panilloma									
Squamous Cen Fapinoma	oi Fapilioilia	1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	` '	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Squamous Cell Papilloma, Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence	Total		` '	Mean 8%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma,	Papilloma, or	Keratoacantho	oma (8%)				0/50 (0%)			
Overall Incidence	Total	4/50 (8%)	` '	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Adenoma					•••••					
		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland:										
Carcinoma or Adenoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male						Female				
#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 Carcinor											
•			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Testes: Adenoma		0/50	(0%)								
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%						
*Thymus: Thymoma Benign		0/48	(0%)				0/50 (0%)				
Overall Incidence	Total	0/48 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma: Benign, Maliç	gnant, NOS										
			(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	(40/)				2/50 (40/)				
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male	Female				
*Thyroid Gland: C-Cell: Carcinoma	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		1700 (270)						
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		3/50 (6%)				2/50 (4%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Tooth: Odontoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	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: Polyp Stromal								
Overall Incidence					Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%
#Uterus: Sarcoma Stromal								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male					Female			
#Uterus: Sarcoma Stromal or Polyp	Stromal									
Overall Incidence					Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%		
#Uterus: Squamous Cell Carcinoma										
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Granular Cell Tumor Benig										
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Polyp										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Schwannoma Malignant							•••••			
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Zymbal's Gland: Carcinoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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

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

^{#:} Denominator is number of animals necropsied