



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

June 2013

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

F1

F2

F3

F4

F5

the data would be shown as:

Male			Female		
M1	M2	M3	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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Version: Jun2013

Contract/Lab: 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

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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
Battelle Columbus Laboratory	052030401	N/A	N/A	0(0)	0(0)	N/A	TEF evaluation (PCB 118)
Female							
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol
Battelle Columbus Laboratory	052030401	03/26/04	733	52(5)	21(616)	383.5	TEF evaluation (PCB 118)

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

Version: Jun2013
 Contract/Lab: 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

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		Male			Female		
#All Organs:							
Benign Tumors							
		27/50 (54%)			40/50 (80%)	43/52 (83%)	
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total 83/102 (81.37%)	Mean 81.35%	SD 1.9%
.....							
#All Organs:							
Malignant Tumors							
		12/50 (24%)			14/50 (28%)	15/52 (29%)	
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total 29/102 (28.43%)	Mean 28.42%	SD 0.6%
.....							
#All Organs:							
Malignant and Benign Tumors							
		33/50 (66%)			46/50 (92%)	48/52 (92%)	
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total 94/102 (92.16%)	Mean 92.15%	SD 0.22%
.....							
#All Organs:							
Hemangiosarcoma							
		1/50 (2%)			1/50 (2%)	1/52 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		1/50 (2%)			1/50 (2%)	1/52 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....							
#All Organs:							
Histiocytic Sarcoma							
		0/50 (0%)			1/50 (2%)	1/52 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 2/102 (1.96%)	Mean 1.96%	SD 0.05%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

	Male				Female			
#All Organs:								
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type								
		0/50 (0%)			0/50 (0%)	2/52 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%
.....								
#All Organs:								
Mesothelioma: Benign, Malignant, NOS								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Mesothelioma: Malignant								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
*Adrenal Cortex:								
Adenoma								
		0/50 (0%)			0/50 (0%)	2/52 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%
.....								
*Adrenal Cortex:								
Carcinoma								
		0/50 (0%)			0/50 (0%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
*Adrenal Medulla:								
Pheochromocytoma Benign								
		5/50 (10%)			0/50 (0%)	3/52 (6%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	3/102 (2.94%)	Mean 2.88%	SD 4.08%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: 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

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		Male			Female		
*Adrenal Medulla:							
 Pheochromocytoma Complex							
		1/50 (2%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Adrenal Medulla:							
 Pheochromocytoma Malignant							
		2/50 (4%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Adrenal Medulla:							
 Pheochromocytoma: Benign, Complex, Malignant, NOS							
		8/50 (16%)			0/50 (0%)	3/52 (6%)	
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total 3/102 (2.94%)	Mean 2.88%	SD 4.08%
.....							
*Brain:							
 Granular Cell Tumor Benign							
		0/50 (0%)			1/50 (2%)	0/52 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/102 (0.98%)	Mean 1%	SD 1.41%
.....							
*Heart:							
 Schwannoma Malignant							
		1/50 (2%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Islets, Pancreatic:							
 Adenoma							
		2/50 (4%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: 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

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 Report Date: 06/17/2013

		Male			Female		
*Islets, Pancreatic:							
 Carcinoma or Adenoma							
		2/50 (4%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Kidney: Renal Tubule:							
 Adenoma							
		1/50 (2%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Kidney: Renal Tubule:							
 Carcinoma or Adenoma							
		1/50 (2%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Liver:							
 Cholangioma							
		0/50 (0%)			0/50 (0%)	1/52 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....							
*Liver:							
 Hepatocellular Adenoma							
		1/50 (2%)			2/50 (4%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 2/102 (1.96%)	Mean 2%	SD 2.83%
.....							
*Liver:							
 Hepatocellular Carcinoma or Hepatocellular Adenoma							
		1/50 (2%)			2/50 (4%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 2/102 (1.96%)	Mean 2%	SD 2.83%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: 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

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	Male				Female			
*Liver:								
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma								
		1/50 (2%)			2/50 (4%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%
.....								
*Lung:								
Alveolar/Bronchiolar Adenoma								
		0/49 (0%)			1/50 (2%)	0/51 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/101 (0.99%)	Mean 1%	SD 1.41%
.....								
*Lung:								
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
		0/49 (0%)			1/50 (2%)	0/51 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/101 (0.99%)	Mean 1%	SD 1.41%
.....								
*Lung:								
Sarcoma								
		0/49 (0%)			1/50 (2%)	0/51 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/101 (0.99%)	Mean 1%	SD 1.41%
.....								
#Lymph Node, Mesenteric:								
Hemangiosarcoma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Mammary Gland:								
Adenoma								
		0/50 (0%)			3/50 (6%)	0/52 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/102 (2.94%)	Mean 3%	SD 4.24%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

		Male			Female		
#Mammary Gland:							
Carcinoma							
		0/50 (0%)			3/50 (6%)	2/52 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 5/102 (4.9%)	Mean 4.92%	SD 1.52%
.....							
#Mammary Gland:							
Carcinoma or Adenoma							
		0/50 (0%)			6/50 (12%)	2/52 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 8/102 (7.84%)	Mean 7.92%	SD 5.77%
.....							
#Mammary Gland:							
Fibroadenoma							
		1/50 (2%)			29/50 (58%)	25/52 (48%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 54/102 (52.94%)	Mean 53.04%	SD 7.02%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma or Adenoma							
		1/50 (2%)			30/50 (60%)	25/52 (48%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 55/102 (53.92%)	Mean 54.04%	SD 8.43%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
		1/50 (2%)			32/50 (64%)	27/52 (52%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 59/102 (57.84%)	Mean 57.96%	SD 8.54%
.....							
#Mammary Gland:							
Myoepithelioma							
		0/50 (0%)			1/50 (2%)	0/52 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/102 (0.98%)	Mean 1%	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: 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

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	Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Oral Mucosa: Squamous Cell Carcinoma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
*Ovary: Granulosa-Theca Tumor Benign								
					1/50 (2%)	0/52 (0%)		
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
*Ovary: Luteoma								
					0/50 (0%)	1/52 (2%)		
Overall Incidence					Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
*Ovary: Tubulostromal Carcinoma								
					1/50 (2%)	0/52 (0%)		
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

		Male			Female		
*Pancreas:							
Adenoma							
		5/50 (10%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Pancreas:							
Carcinoma or Adenoma							
		5/50 (10%)			0/50 (0%)	0/52 (0%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 0/102 (0%)	Mean 0%	SD 0%
.....							
*Pituitary Gland: Pars Distalis or Unspecified Site:							
Adenoma							
		5/50 (10%)			18/50 (36%)	17/52 (33%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 35/102 (34.31%)	Mean 34.35%	SD 2.34%
.....							
*Pituitary Gland: Pars Distalis or Unspecified Site:							
Carcinoma							
		0/50 (0%)			0/50 (0%)	2/52 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 2/102 (1.96%)	Mean 1.92%	SD 2.72%
.....							
*Pituitary Gland: Pars Distalis or Unspecified Site:							
Carcinoma or Adenoma							
		5/50 (10%)			18/50 (36%)	19/52 (37%)	
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 37/102 (36.27%)	Mean 36.27%	SD 0.38%
.....							
*Salivary Glands:							
Schwannoma Malignant							
		1/50 (2%)			0/50 (0%)	0/51 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 0/101 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Skeletal Muscle:									
Sarcoma									
		0/50	(0%)			1/50	(2%)	0/52	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	1/102	(0.98%)	Mean 1%	SD 1.41%
.....									
#Skin:									
Basal Cell Carcinoma									
		1/50	(2%)			0/50	(0%)	0/52	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	0/102	(0%)	Mean 0%	SD 0%
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		1/50	(2%)			0/50	(0%)	0/52	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	0/102	(0%)	Mean 0%	SD 0%
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		1/50	(2%)			0/50	(0%)	0/52	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	0/102	(0%)	Mean 0%	SD 0%
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		6/50	(12%)			0/50	(0%)	1/52	(2%)
Overall Incidence	Total	6/50	(12%)	Mean 12%	SD 0%	1/102	(0.98%)	Mean 0.96%	SD 1.36%
.....									
#Skin:									
Fibroma									
		5/50	(10%)			1/50	(2%)	2/52	(4%)
Overall Incidence	Total	5/50	(10%)	Mean 10%	SD 0%	3/102	(2.94%)	Mean 2.92%	SD 1.31%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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	Male				Female			
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
		7/50 (14%)			2/50 (4%)	2/52 (4%)		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	4/102 (3.92%)	Mean 3.92%	SD 0.11%
.....								
#Skin:								
Fibrosarcoma								
		1/50 (2%)			1/50 (2%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		2/50 (4%)			1/50 (2%)	0/52 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Fibrous Histiocytoma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangiosarcoma								
		0/50 (0%)			1/50 (2%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....								
#Skin:								
Keratoacanthoma								
		4/50 (8%)			0/50 (0%)	1/52 (2%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

	Male				Female			
#Skin:								
Neurofibrosarcoma or Schwannoma (malignant or NOS)								
		0/50 (0%)			1/50 (2%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....								
#Skin:								
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)								
		0/50 (0%)			1/50 (2%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....								
#Skin:								
Schwannoma Malignant								
		0/50 (0%)			1/50 (2%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%
.....								
#Skin:								
Squamous Cell Carcinoma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma								
		2/50 (4%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
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	Male				Female			
#Skin:								
Squamous Cell Papilloma or Papilloma								
		1/50 (2%)			0/50 (0%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
		5/50 (10%)			0/50 (0%)	1/52 (2%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Skin:								
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma								
		5/50 (10%)			0/50 (0%)	1/52 (2%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Stomach, Forestomach:								
Squamous Cell Carcinoma								
		1/50 (2%)			1/50 (2%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
#Stomach, Forestomach:								
Squamous Cell Carcinoma or Papilloma Squamous								
		1/50 (2%)			1/50 (2%)	0/52 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
.....								
*Testes:								
Adenoma								
		3/49 (6%)						
Overall Incidence	Total	3/49 (6.12%)	Mean 6.12%	SD 0%				

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

		Male			Female		
*Thymus:							
Thymoma Benign							
		1/46 (2%)			0/47 (0%)	0/51 (0%)	
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/98 (0%)	Mean 0% SD 0%
.....							
*Thymus:							
Thymoma: Benign, Malignant, NOS							
		1/46 (2%)			0/47 (0%)	0/51 (0%)	
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/98 (0%)	Mean 0% SD 0%
.....							
*Thyroid Gland: C-Cell:							
Adenoma							
		13/50 (26%)			11/49 (22%)	9/51 (18%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	20/100 (20%)	Mean 20.05% SD 3.4%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma							
		0/50 (0%)			0/49 (0%)	2/51 (4%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 1.96% SD 2.77%
.....							
*Thyroid Gland: C-Cell:							
Carcinoma or Adenoma							
		13/50 (26%)			11/49 (22%)	11/51 (22%)	
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	22/100 (22%)	Mean 22.01% SD 0.62%
.....							
*Thyroid Gland: Follicular Cell:							
Adenoma							
		0/50 (0%)			0/49 (0%)	1/51 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 0.98% SD 1.39%
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

	Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%)			0/49 (0%)	1/51 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 0.98%	SD 1.39%
.....								
#Tooth: Odontoma								
		0/50 (0%)			0/50 (0%)	1/52 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
.....								
#Uterus: Carcinoma								
					0/50 (0%)	2/52 (4%)		
Overall Incidence					Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%
.....								
#Uterus: Polyp Stromal								
					10/50 (20%)	3/52 (6%)		
Overall Incidence					Total	13/102 (12.75%)	Mean 12.88%	SD 10.06%
.....								
#Uterus: Sarcoma Stromal								
					2/50 (4%)	0/52 (0%)		
Overall Incidence					Total	2/102 (1.96%)	Mean 2%	SD 2.83%
.....								
#Uterus: Sarcoma Stromal or Polyp Stromal								
					12/50 (24%)	3/52 (6%)		
Overall Incidence					Total	15/102 (14.71%)	Mean 14.88%	SD 12.89%
.....								

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013

Contract/Lab: 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

Report Date: 06/17/2013

	Male			Female		
#Uterus:						
Schwannoma Malignant						
			0/50 (0%)	1/52 (2%)		
Overall Incidence		Total	1/102 (0.98%)	Mean 0.96%	SD	1.36%
.....						
#Vagina:						
Polyp						
			1/50 (2%)	1/52 (2%)		
Overall Incidence		Total	2/102 (1.96%)	Mean 1.96%	SD	0.05%
.....						
#Vagina:						
Schwannoma Malignant						
			1/50 (2%)	0/52 (0%)		
Overall Incidence		Total	1/102 (0.98%)	Mean 1%	SD	1.41%
.....						
#Vagina:						
Squamous Cell Carcinoma						
			0/50 (0%)	1/52 (2%)		
Overall Incidence		Total	1/102 (0.98%)	Mean 0.96%	SD	1.36%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied