

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
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: 06/17/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000603 052030401	03/14/07 N/A	727 N/A	50(3) 0(0)	20(644) 0(0)	584.8 N/A	Indole-3-carbinol TEF evaluation (PCB 118)
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000603 052030401	03/15/07 03/26/04	729 733	50(5) 52(5)	21(637) 21(616)	353.0 383.5	Indole-3-carbinol TEF evaluation (PCB 118)

Contract/Lab: 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%)	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 Tu	ımors								
		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 He	mangioma								
		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

Contract/Lab: 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: 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, N	Malignant, NOS											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/102 (0%)	0/52 (0%) Mean 0%	SD 0%				
#All Organs: Mesothelioma: Malignant	t	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 Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 2/102 (1.96%)	2/52 (4%) Mean 1.92%	SD 2.72%				
*Adrenal Cortex: Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/102 (0.98%)	1/52 (2%) Mean 0.96%	SD 1.36%				
*Adrenal Medulla: Pheochromocytoma Ben	ign	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

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: 7

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Co	omplex							
	-	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 M	alignant							
•	•	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: B Overall Incidence	Benign, Complex, Total	Malignant, NOS 8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	0/50 (0%) 3/102 (2.94%)	3/52 (6%) Mean 2.88%	SD 4.08%
Brain: Granular Cell Tumor B		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 Malignar								
		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%
lslets, Pancreatic: Adenoma		0(50 (45))				0/50 (00)	0/50 (00/)	
	T	2/50 (4%)		OD 00/	+	0/50 (0%)	0/52 (0%)	00.00/
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

*Islets, Pancreatic: Carcinoma or Adenoma

Overall Incidence

Overall Incidence

Overall Incidence

Cholangioma

Overall Incidence

Overall Incidence

Overall Incidence

*Liver:

*Liver:

*Liver:

*Kidney: Renal Tubule: Carcinoma or Adenoma

.....

Hepatocellular Adenoma

Adenoma

*Kidney: Renal Tubule: **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

SD 0%

SD 0%

Male **Female** 0/50 (0%)0/52 (0%)Mean 4% SD 0% Total 0/102 (0%) Mean 0% SD 0% 0/50 (0%)0/52 (0%)Mean 2% SD 0% Total 0/102 (0%) Mean 0% SD 0% 0/50 (0%)0/52 (0%)Mean 2% SD 0% Total 0/102 (0%) Mean 0% SD 0% 0/50 (0%)1/52 (2%)Mean 0% SD 0% Total 1/102 (0.98%) Mean 0.96% SD 1.36%

2/50

2/50

2/102 (1.96%)

2/102 (1.96%)

Total

Total

(4%)

(4%)

0/52

0/52

(0%)

(0%)

SD 2.83%

SD 2.83%

Mean 2%

Mean 2%

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Report Date: 06/17/2013

*:	De	no	miı	nato	r is	nun	nber	of	an	imals	with	tissues	exar	mined	l mic	rosco	pically	/

Hepatocellular Carcinoma or Hepatocellular Adenoma

Total

Total

Total

Total

Total

Total

2/50

2/50 (4%)

1/50

1/50 (2%)

1/50

1/50 (2%)

0/50

0/50 (0%)

1/50

1/50 (2%)

1/50

1/50 (2%)

(4%)

(2%)

(2%)

(0%)

(2%)

(2%)

Mean 2%

Mean 2%

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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					
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma												
0	T-1-1	1/50 (2%)	M 00/	00.00/	Taral	2/50 (4%)	0/52 (0%)	OD 0.00%				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%				
*Lung: Alveolar/Bronchiolar A	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 C Overall Incidence	Carcinoma or Alve	eolar/Bronchiolar Adeno 0/49 (0%) 0/49 (0%)	ma Mean 0%	SD 0%	Total	1/50 (2%) 1/101 (0.99%)	0/51 (0%) Mean 1%	SD 1.41%				
*Lung: Sarcoma Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/101 (0.99%)	0/51 (0%) Mean 1%	SD 1.41%				
#Lymph Node, Mesenter Hemangiosarcoma	ic:											
	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/102 (0%)	0/52 (0%) Mean 0%	SD 0%				
Overall Incidence			IVICALL Z/0	3D 070	i olai	0/102 (0/0)	MEAN 070	3D 070				
Overall Incidence	ı Olal											
Overall Incidence #Mammary Gland: Adenoma	Total	0/50 (0%)				3/50 (6%)	0/52 (0%)					

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: 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	
	0/50	(0%)				3/50 (6%)	2/52 (4%)	
Total	, ,			SD 0%	Total	5/102 (4.9%)	Mean 4.92%	SD 1.52%
ı								
		(0%)				, ,	2/52 (4%)	
Total	0/50 (0%)		Mean 0%	SD 0%	Total	8/102 (7.84%)	Mean 7.92%	SD 5.77%
		(2%)		05 00/		` ,	,	05 - 000/
l otal	1/50 (2%)		Mean 2%	SD 0%	l otal	54/102 (52.94%)	Mean 53.04%	SD 7.02%
or Adenoma		(201)				20/20 (2001)	07/70 (4004)	
Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	30/50 (60%) 55/102 (53.92%)	25/52 (48%) Mean 54.04%	SD 8.43%
		(2%)				32/50 (64%)	27/52 (52%)	
Total	1/50 (2%)		Mean 2%	SD 0%	Total	59/102 (57.84%)	Mean 57.96%	SD 8.54%
	0/50	(00/)				4/50 /29/)	0/52 (00/)	
Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	, ,	SD 1.41%
	a, Carcinoma, or Total	Total 0/50 (0%) 0/50 Total 0/50 (0%) 1/50 Total 1/50 (2%) a or Adenoma 1/50 Total 1/50 (2%) a, Carcinoma, or Adenoma 1/50 Total 1/50 (2%)	Total 0/50 (0%) O/50 (0%) Total 0/50 (0%) 1/50 (2%) Total 1/50 (2%) Total 1/50 (2%) Total 1/50 (2%) A, Carcinoma, or Adenoma 1/50 (2%) Total 1/50 (2%) Total 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 1/50 (2%) Total 1/50 (2%) Mean 2% a or Adenoma 1/50 (2%) Total 1/50 (2%) Mean 2% A, Carcinoma, or Adenoma 1/50 (2%) Total 1/50 (2%) Mean 2% Mean 2% Mean 2%	750 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Mean 2% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 1/50 (2%) SD 0% Total 1/50 (2%) Total 1/50 (2%) SD 0% Total	Total 0/50 (0%) Mean 0% SD 0% Total 5/102 (4.9%) O/50 (0%)	O/50 (0%) Mean 0% SD 0% Total 5/102 (4.9%) Mean 4.92%

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

^{#:} Denominator is number of animals necropsied

Overall Incidence

Overall Incidence

#Oral Mucosa:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Squamous Cell Carcinoma

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/17/2013 Route: GAVAGE Vehicle: CORN OIL **Female** 0/50 (0%)0/52 (0%)SD 0% Total 0/102 (0%) Mean 0% SD 0% 0/50 (0%)0/52 (0%)

0/102 (0%)

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Mean 0%

(0%)Mean 0%

0/52

SD 0%

SD 0%

Squamous Cell Carcinoma						
		1/50 (2%)				0/50 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)

Male

Mean 2%

Mean 2%

*Ovary: **Granulosa-Theca Tumor Benign**

1/50 (2%)0/52 (0%)**Overall Incidence** Total 1/102 (0.98%) Mean 1% SD 1.41%

SD 0%

Total

*Ovary: Luteoma

0/50 (0%)1/52 (2%)**Overall Incidence** Total 1/102 (0.98%) Mean 0.96% SD 1.36%

Tubulostromal Carcinoma 1/50 (2%)0/52 (0%)

Overall Incidence 1/102 (0.98%) Mean 1% SD 1.41% Total

*: Denominator is number of animals with tissues examined microscopically

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma

Total

Total

1/50

1/50 (2%)

1/50

1/50 (2%)

(2%)

#: Denominator is number of animals necropsied

Contract/Lab: 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	
*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 Distali: Adenoma	s or Unspeci	fied Site:						
		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 Distali 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 Distali 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		(Fa)				- (ac.)	(00)	
		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

Contract/Lab: 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: 06/17/2013

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			Male		Female				
#Skeletal Muscle: Sarcoma									
		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%	
#Skin: Basal Cell Carcinoma		(50)				2/22 (221)	- ()		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/102 (0%)	0/52 (0%) Mean 0%	SD 0%	
	TOlai	1/30 (2/6)		30 0%	10tai		iviean 070		
#Skin: Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N 1/50 (2%)	OS)			0/50 (0%)	0/52 (0%)		
	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%	
Overall Incidence	ı Olal	1700 (270)							
#Skin:	Basal Cell Adend	oma, Basosquamous Tur					0/52 (0%)		
#Skin: Basal Cell Carcinoma,	Basal Cell Adend				Total	0/50 (0%) 0/102 (0%)	0/52 (0%) Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Basal Cell Adencioma Total noma, Carcinoma	nma, Basosquamous Tur 1/50 (2%) 1/50 (2%) a, Basosq. Tumor (M or E	mor (benign, maligna Mean 2% B), Basal Cell Adeno	ant or SD 0%	Total	0/50 (0%) 0/102 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Basal Cell Adencioma Total noma, Carcinoma	nma, Basosquamous Tur 1/50 (2%) 1/50 (2%) a, Basosq. Tumor (M or E	mor (benign, maligna Mean 2% B), Basal Cell Adeno	ant or SD 0%	Total Total	0/50 (0%)	` ,	SD 0% SD 1.36%	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Basal Cell Adencioma Total noma, Carcinoma	1/50 (2%) 1/50 (2%) 1/50 (2%) a, Basosq. Tumor (M or E atoacanthoma, Trichoep 6/50 (12%)	mor (benign, maligna Mean 2% 3), Basal Cell Adeno ithelioma	SD 0%		0/50 (0%) 0/102 (0%) 0/50 (0%)	Mean 0% / / / / / / / / / / / / / / / / / /		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

		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										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/102 (0.98%)	0/52 (0%) Mean 1%	SD 1.41%		
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma	, or Fibrous Histiocytoma 2/50 (4%)	a			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										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 2/102 (1.96%)	1/52 (2%) 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

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date: 06/17/2013

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

Vehicle: CORN OIL

		Male				Female				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)										
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 2/102 (1.96%)	1/52 (2%) Mean 1.96%	SD 0.05%			
ırofibroma, or S		lignant or NOS)								
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 2/102 (1.96%)	1/52 (2%) Mean 1.96%	SD 0.05%			
	0/50 (0%)				1/50 (2%)	1/52 (2%)				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%			
na	1/50 (2%)				0/50 (0%)	0/52 (0%)				
Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%			
na, Basal Cell C	•	us Tumor (malignar	at or NOS),		0/50 (0%)	0/52 (0%)				
Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%			
ıa	4/50 (004)				0/50 (00)	0/50 (00/)				
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/102 (0%)	0/52 (0%) Mean 0%	SD 0%			
	Total Total Total Total Total Total Total Total	0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) rofibroma, or Schwannoma (benign, ma 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) ma, Basal Cell Carcinoma, Basosquamor 2/50 (4%) Total 2/50 (4%)	Chwannoma (malignant or NOS) 0/50 (0%) Total 0/50 (0%) Mean 0% Irofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% Mean 0% 1/50 (2%) Total 1/50 (2%) Mean 2% ma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS) 0/50 (0%) Total 2/50 (4%) Total 2/50 (4%) Mean 4%	Chwannoma (malignant or NOS) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Profibroma, or Schwannoma (benign, malignant or NOS) 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% Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% Man, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), 2/50 (4%) Total 2/50 (4%) Mean 4% SD 0%	Chwannoma (malignant or NOS) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total 1/50 (2%) Mean 0% SD 0% Total Ma 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total ma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), 2/50 (4%) Total 2/50 (4%) Mean 4% SD 0% Total	Chwannoma (malignant or NOS) 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Profibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Total 1/50 (2%) Mean 0% SD 0% Total 0/102 (0%) ma 1/50 (2%) Mean 2% SD 0% Total 0/102 (0%) ma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), 2/50 (4%) Mean 4% SD 0% Total 0/102 (0%) Total 2/50 (4%) Mean 4% SD 0% Total 0/102 (0%)	Chwannoma (malignant or NOS) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% rrofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% Total 0/50 (0%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% ma 1/50 (2%) Mean 0% SD 0% Total 2/102 (1.96%) Mean 1.96% ma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Mean 0% Total 0/50 (0%) Mean 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 16

Report Date: 06/17/2013

Species: RATS

Route: GAVAGE

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

Vehicle: CORN OIL

			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 Papillo	ma. Papilloma. S	Squamous Cell Carcinom	na or Keratoacanthom	na						
	., .,	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%		
Squamous Cell Papillo Overall Incidence #Stomach, Forestomach Squamous Cell Carcine	Total :	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 1/102 (0.98%)	1/52 (2%) Mean 0.96%	SD 1.36%		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/102 (0.98%)	0/52 (0%) Mean 1%	SD 1.41%		
#Stomach, Forestomach Squamous Cell Carcin Overall Incidence		a Squamous 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/102 (0.98%)	0/52 (0%) Mean 1%	SD 1.41%		
*Testes:		······								
Adenoma		3/49 (6%)								

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			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, Malign										
		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 Ce Adenoma	ell:									
		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

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:** 18

			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%)	00.0700/		
Overall Incidence					Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%		
#Uterus: Polyp Stromal						10/50 (000)	2(72)			
Overall Incidence					Total	10/50 (20%) 13/102 (12.75%)	3/52 (6%) 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 Po	lyp 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

Contract/Lab: 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	
#Uterus:				
Schwannoma Malignant		0/50 (00/)	4/50 (00/)	
Overell lesidense	Tatal	0/50 (0%)	1/52 (2%)	CD 4.269/
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	, ,	Mean 1%	SD 1.41%
	Total	1/102 (0.98%)		
#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