Contract/Lab: 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 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 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 (40))				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%

Page: 8

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					
#Mammary Gland: Carcinoma												
	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%)

Page: 11

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		(Fig. (Fig.)				- (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

Page: 13

			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		()				2/52 (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%				
#Skin: Basal Cell Carcinoma o	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 Olai							
#Skin:	Basal Cell Adend	oma, Basosquamous Tur		ant or			0/52 (0%)	
#Skin: Basal Cell Carcinoma,	Basal Cell Adend			ant or SD 0%	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 Batoacanthoma, Trichoep	mor (benign, maligna Mean 2% 3), Basal Cell Adeno	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%)	mor (benign, maligna Mean 2% 3), Basal Cell Adeno	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 Carcinoma, Adenoma, Papilloma, S	Basal Cell Adencioma Total noma, Carcinoma	1/50 (2%) 1/50 (2%) 1/50 (2%) a, Basosq. Tumor (M or Batoacanthoma, Trichoep 6/50 (12%)	Mean 2% Mean Adeno B), Basal Cell Adeno Sithelioma	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 Report Date: 06/17/2013

		Male Female											
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 7/50 (14%) 2/50 (4%) 2/50 (4%) 2/50 (4%) 3/70 (44%)													
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 /09/\	1/52 (29/)						
		4/50 (8%)				0/50 (0%)	1/52 (2%)						

^{*:} 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

Page: 15

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) 1/50 (2%) 1/52 (2%)													
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: Neurofibrosarcoma, Neuro	fibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS)			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%)		05.00/		0/50 (0%)	0/52 (0%)	05 00/					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%					
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t or NOS),									
		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													
Occupation of James	Taral	1/50 (2%)	Maran 00/	00.00/	T-1-1	0/50 (0%)	0/52 (0%)	OD 00/					
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

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

					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	a or Keratoacanthom	ıa						
	., .,	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			Mean 2%	SD 0%	Total	1/50 (2%) 1/102 (0.98%)	0/52 (0%) Mean 1%	SD 1.41%		
*Testes: Adenoma	Total	3/49 (6%)	IVICALI Z/O	JU 0/6	i otal	1/102 (0.30/6)	iviedii 170	3D 1.4170		
		3/49 (6.12%)								

^{*:} 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/)	
Overall Incidence	-	Total	0/50 (0%) 1/102 (0.98%)	1/52 (2%) 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			4/50 (00/)	0/50 (00/)	
Overall Incidence		Total	1/50 (2%)	0/52 (0%)	CD 4 440/
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