

NTP Historical Controls Report

By Route and Vehicle

Wistar Han RATS

November 2014

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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Page: 4

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

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				
Southern Research Institute Battelle Columbus Laboratory	052020903 052032003	08/26/08 07/25/07	729 727	49(3) 50(3)	36(671) 33(642)	673.4 662.9	Pentabromodiphenyl oxide (technical) (DE 71) Tetrabromobisphenol A		
Female									
Southern Research Institute Battelle Columbus Laboratory	052020903 052032003	08/26/08 07/26/07	732 728	50(5) 50(5)	37(678) 34(678)	389.6 375.2	Pentabromodiphenyl oxide (technical) (DE 71) Tetrabromobisphenol A		

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

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								
		33/49 (67%)	30/50 (60%)			37/50 (74%)	38/50 (76%)	
Overall Incidence	Total	63/99 (63.64%)	Mean 63.67%	SD 5.2%	Total	75/100 (75%)	Mean 75%	SD 1.41%
#All Organs: Malignant Tumors								
		13/49 (27%)	8/50 (16%)			10/50 (20%)	10/50 (20%)	
Overall Incidence	Total	21/99 (21.21%)	Mean 21.27%	SD 7.45%	Total	20/100 (20%)	Mean 20%	SD 0%
#All Organs: Malignant and Benign Tı	umors	36/49 (73%)	34/50 (68%)			40/50 (80%)	40/50 (80%)	
Overall Incidence	Total	70/99 (70.71%)	Mean 70.73%	SD 3.87%	Total	80/100 (80%)	Mean 80%	SD 0%
#All Organs: Hemangioma		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		8/49 (16%)	3/50 (6%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	SD 7.3%	Total	4/100 (4%)	Mean 4%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		9/49 (18%)	4/50 (8%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	13/99 (13.13%)	Mean 13.18%	SD 7.33%	Total	4/100 (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: Wistar Han

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								
•		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocyti	c, Monocytic, Mo	ononuclear, or Undiffere	ntiated					
	-	1/49 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Overall Incidence	Total	phocytic, Mixed, NOS, or 0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	I Type SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign		;				(201)	(00)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Maligna	ınt							
		0/49 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	25 22/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/40 /627	0/50 (05)			0/50 (00)	0/50 (00)	
	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence								

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Osteosarcoma								
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%)	0/50 (0%) Mean 1%	CD 4 440/
Overall incidence	Total	0/99 (0%)	wean 0%	SD 0%	Total	1/100 (1%)	wean 1%	SD 1.41%
#All Organs: Osteosarcoma or Osteoma		-1						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
	10tai	0/99 (0%)		3D 0%		1/100 (1%)		3D 1.41%
*Adrenal Cortex: Adenoma								
Overall Insidence	Tatal	0/49 (0%)	0/50 (0%)	CD 00/	Tatal	1/50 (2%)	1/50 (2%)	CD 00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Carcinoma								
Occupation of the second	T-1-1	1/49 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Benign								
		0/49 (0%)	0/49 (0%)			1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
*Adrenal Medulla: Pheochromocytoma Comple	ex							
		0/49 (0%)	0/49 (0%)			1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Malignant												
		1/49 (2%)	0/49 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Bo	enign, Complex	, Malignant, NOS										
		1/49 (2%)	0/49 (0%)			2/50 (4%)	2/49 (4%)					
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%				
#Blood Vessel: Hemangiosarcoma		0/40 /00/)	4/50 /00/			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
		, ,			10tai							
*Bone Marrow: Hemangiosarcoma												
	.	0/49 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma												
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma												
		0/49 (0%)	0/50 (0%)	00.00		1/50 (2%)	0/50 (0%)	00				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

			Male				Female	
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Bone: Sarcoma	•••••							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma Malignant	•	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benigi			•••••					
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Maligr	nant	0/40 (00/)	0/50 (0%)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female					
*Brain: Meningioma Malignant 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Brain:	lianent NOS											
Meningioma: Benign, Ma	ilighant, NOS	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glio	ma, or Astrocy	/toma 1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma		1/49 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma or Adenoma												
		1/49 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Heart: Schwannoma Benign		0/40 /00/	0/50 /00/			0/50 (00/)	4/50 (20/)					
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
*Heart: Schwannoma NOS								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Fibroma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Leiomyoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Fibroma	ified:							
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 12

			Male				Female						
#Intestine Small: Site Unspecified: Leiomyoma													
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Intestine Small: Site Uns Leiomyosarcoma	specified:				•••••								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%					
*Islets, Pancreatic: Adenoma		4/40 (00)	4/50 (00/)			0/50 (00/)	0/50 (00)						
Overall Incidence	Total	4/49 (8%) 5/99 (5.05%)	1/50 (2%) Mean 5.08%	SD 4.36%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
*Islets, Pancreatic: Carcinoma						0/50 (0%)	0/50 (00/)						
Overall Incidence	Total	2/49 (4%) 2/99 (2.02%)	0/50 (0%) Mean 2.04%	SD 2.89%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
*Islets, Pancreatic: Carcinoma or Adenoma													
Overall Incidence	Total	6/49 (12%) 7/99 (7.07%)	1/50 (2%) Mean 7.12%	SD 7.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
*Kidney: Pelvis and Trans Papilloma	sitional Epitheliu				•••••								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 13

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/40 (00)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma		0/40 /00/)	0/50 (00/)			0/50 (00/)	0/50 (004)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/40 /65:1	0/50 (00.1)			0/50 (00/)	4/50 (004)	
Overall Incidence	Total	3/49 (6%) 3/99 (3.03%)	0/50 (0%) Mean 3.06%	SD 4.33%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

		Male				Female				
na or Hepatoce	Ilular Adenoma									
•	3/49 (6%)	0/50 (0%)			3/50 (6%)	1/50 (2%)				
Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	4/100 (4%)	Mean 4%	SD 2.83%			
na, Hepatocellu	ılar Adenoma, or Hepatol	olastoma								
•	3/49 (6%)	0/50 (0%)			3/50 (6%)	1/50 (2%)				
Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	4/100 (4%)	Mean 4%	SD 2.83%			
enoma	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
					0/50 (0%)	0/50 (0%)				
Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
•••••										
	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
:	4/40 /00/	4/50 (20/)			0/50 (00/)	0/50 (09/)				
Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
	Total Total Total Total Henoma Total Total Total Total Total	Total 3/99 (3.03%) na, Hepatocellular Adenoma, or Hepatol 3/49 (6%) Total 3/99 (3.03%) lenoma 0/49 (0%) Total 0/99 (0%) rcinoma or Alveolar/Bronchiolar Adeno 0/49 (0%) Total 0/99 (0%) Total 0/99 (0%) Total 0/99 (0%) : 1/49 (2%)	Total 3/99 (3.03%) Mean 3.06% Total 3/99 (3.03%) Mean 3.06% Total 3/99 (3.03%) Mean 3.06% Total 3/99 (6%) 0/50 (0%) Total 3/99 (3.03%) Mean 3.06% Henoma 0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% Total 0/99 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% Total 0/99 (0%) Mean 0%	na or Hepatocellular Adenoma						

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 15 Report Date: 11/11/2014

			Male		0/50 (0%) 4/50 (8%) Total 4/100 (4%) Mean 4% SD 5.669 1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% SD 0% 1/50 (2%) 4/50 (8%) Total 5/100 (5%) Mean 5% SD 4.249			
#Lymph Node, Mesenteric: Hemangiosarcoma								
		7/49 (14%)	1/50 (2%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	8/99 (8.08%)	Mean 8.14%	SD 8.69%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Mammary Gland: Adenoma								
		0/49 (0%)	0/50 (0%)			` ,	4/50 (8%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%		, ,	Mean 4%	SD 5.66%
#Mammary Gland: Carcinoma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 4.24%
#Mammary Gland: Fibroadenoma								
		0/49 (0%)	1/50 (2%)			9/50 (18%)	8/50 (16%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	17/100 (17%)	Mean 17%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenoma or	· Adenoma							
		0/49 (0%)	1/50 (2%)			9/50 (18%)	12/50 (24%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	21/100 (21%)	Mean 21%	SD 4.24%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

			Male			Female					
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma											
		0/49 (0%)	1/50 (2%)			10/50 (20%)	12/50 (24%)				
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	22/100 (22%)	Mean 22%	SD 2.83%			
#Mesentery: Hemangiosarcoma											
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Lipoma											
		1/49 (2%)	0/50 (0%)	00		0/50 (0%)	0/50 (0%)	22.00/			
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Schwannoma Malignant		2(42 (224)	0/50 (00/)			0/50 (00/)	0(50 (004)				
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
		` '									
*Nose: Chondroma											
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
*Nose: Olfactory Neuroblastoma											
		0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

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: 11/11/2014

Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/49 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#Oral Mucosa: Squamous Cell Carcinoma** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% *Ovary: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% **Granulosa Cell Tumor Benign** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41%

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 18

			Male				Female	
*Ovary: Granulosa Cell Tumor Ma	llignant					4/50 (001)	4/50 (00)	
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	ant, NOS						
Overall Incidence					Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
*Ovary: Sex Cord Stromal Tumor,	Benign					0/50 /00/	0/50 (40/)	
Overall Incidence					Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	1/46 (2%) 2/96 (2.08%)	1/50 (2%) Mean 2.09%	SD 0.12%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	1/46 (2%) 2/96 (2.08%)	1/50 (2%) Mean 2.09%	SD 0.12%	Total	0/50 (0%) 0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
Parathyroid Gland:								
		2/47 (4%)	0/45 (0%)			1/49 (2%)	0/48 (0%)	
Overall Incidence	Total	2/92 (2.17%)	Mean 2.13%	SD 3.01%	Total	1/97 (1.03%)	Mean 1.02%	SD 1.44%
Pituitary Gland: Pars Distali Adenoma	s or Unspec	ified Site:						
		19/49 (39%)	21/50 (42%)			23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%	Total	44/100 (44%)	Mean 44%	SD 2.83%
Pituitary Gland: Pars Distali Carcinoma		ified Site:				0/50 (00/)	0/50 (00/)	
		0/49 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distali Carcinoma or Adenoma	s or Unspec	ified Site:						
		19/49 (39%)	21/50 (42%)			23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%	Total	44/100 (44%)	Mean 44%	SD 2.83%
Pituitary Gland: Pars Interm								
		0/49 (0%)	2/50 (4%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/49 (0%)	2/50 (4%)			1/50 (2%)	4/50 (8%)	
Overall Incidence		2/99 (2.02%)				5/100 (5%)		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
*Prostate: Adenoma		2/12 / (251)						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Adenoma								
Overall Incidence	Total	1/46 (2%) 1/96 (1.04%)	0/50 (0%) Mean 1.09%	SD 1.54%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	1/46 (2%) 1/96 (1.04%)	0/50 (0%) Mean 1.09%	SD 1.54%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Salivary Glands: Myoepithelioma		0/40 /(00/)	4/50 (00%)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/46 (0%) 1/96 (1.04%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (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: Wistar Han

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%) 0/50 (0%) 4% Total 0/100 (0%) Mean 0% SD 0			
*Salivary Glands: Schwannoma Malignant								
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		4/40 (00)	0/50 /00/			0/50 (00/)	0/50 (00()	
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	` '	,	SD 0%
#Skeletal Muscle: Sarcoma		0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
Overall Incidence	Total	1/49 (2%) 3/99 (3.03%)	2/50 (4%) Mean 3.02%	SD 1.39%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma or Ba		s Tumor Benign 1/49 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/99 (3.03%)	Mean 3.02%	SD 1.39%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

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

nor incidence for Selected Control A **Route:** GAVAGE

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female			
#Skin:		Tumor Bonian or Trickes	nithaliama					
basai Celi Adenoma, b	asosquamous i	Tumor Benign, or Trichoe 1/49 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/99 (3.03%)	Mean 3.02%	SD 1.39%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma								
		0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant or N	OS)					
		0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tur		nt or		4/50 (00)	0/50 (00/)	
Overall Incidence	Total	1/49 (2%) 3/99 (3.03%)	2/50 (4%) Mean 3.02%	SD 1.39%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Overall incluence	10tai		Wear 3.02%		I Ulai	1/100 (1%)		30 1.41%
		na, Basosq. Tumor (M or leratoacanthoma, Trichoep 3/49 (6%)		na,		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	10/99 (10.1%)	Mean 10.06%	SD 5.57%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Fibroma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 23

			Male				Female				
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 1/49 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overell Institute 20											
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma											
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	a, or Fibrous Histiocytom 0/49 (0%)	a 0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Hamartoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma											
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
#Skin: Keratoacanthoma		2/49 (4%)	4/EO (99/\			0/50 /09/\	0/50 (09/)				
Overall Incidence	Total	2/49 (4%) 6/99 (6.06%)	4/50 (8%) Mean 6.04%	SD 2.77%	Total	0/50 (0%) 0/100 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09			
#Skin: Lipoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 00/
			ivicali 070		ı Olai		ivicali 076	
#Skin: Liposarcoma								
		0/49 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or Sch	wannoma (n	0/49 (0%)	2/50 (4%)			` '	` '	
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neuro				SD 2.83%	Total	` '	` '	SD 0%
#Skin: Schwannoma Malignant		0/49 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence		(,				` '		

^{*:} 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

Vehicle: CORN OIL

trol Animal Groups Report Date: 11/11/2014

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Strain: Wistar Han Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
Occupation of days as	Tatal	0/49 (0%)	1/50 (2%)	00 4 440/	Tatal	0/50 (0%)	0/50 (0%)	05 , 00/
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma	0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma	0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:		Squamous Cell Carcinom 2/49 (4%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	7/99 (7.07%)	Mean 7.04%	SD 4.18%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, c	or Keratoacanthoma 2/49 (4%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	7/99 (7.07%)	Mean 7.04%	SD 4.18%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma			(0.5)				(201)	
Overell Incidence	Total	0/49 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male			Female				
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma										
		1/47 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/97 (2.06%)	Mean 2.06%	SD 0.09%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Fibrosarcoma										
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Leiomyoma										
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Leiomyosarcoma										
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Sarcoma										
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

		Male			Female							
#Stomach, Forestomach: Squamous Cell Carcinoma 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
	` '	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%					
	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%					
	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%					
	0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)						
Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
	0/40 (00/)	0/50 /00/			0/50 (00%)	0/50 /00/						
Total	` '	` ,	SD 0%	Total	` ,	` ,	SD 0%					
	Total Total	Total 0/99 (0%) or Papilloma Squamous 1/49 (2%) Total 1/99 (1.01%) 1/49 (2%) Total 1/99 (1.01%) 1/49 (2%) Total 1/99 (1.01%) Total 0/49 (0%) Total 0/49 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% Or Papilloma Squamous 1/49 (2%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% 1/49 (2%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% 1/49 (2%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% 1/49 (2%) 0/50 (0%) Total 0/49 (0%) 0/50 (0%) Total 0/49 (0%) 0/50 (0%) Total 0/49 (0%) 0/50 (0%)	O/49 (0%) O/50 (0%) Total O/99 (0%) Mean 0% SD 0% Or Papilloma Squamous 1/49 (2%) O/50 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% 1/49 (2%) O/50 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 1/99 (1.01%) Mean 1.02% SD 1.44% O/49 (0%) O/50 (0%) Total 0/99 (0%) Mean 0% SD 0%	0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0% Total Fapilloma Squamous 1/49 (2%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 1/49 (2%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total Total 0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0% Total 0/49 (0%) 0/50 (0%) SD 0% Total	0/49 (0%) 0/50 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) or Papilloma Squamous 1/49 (2%) 0/50 (0%) 0/50 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/100 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/100 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/100 (0%) Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/100 (0%) Total 0/99 (0%) 0/50 (0%) SD 0% Total 1/100 (1%) 0/49 (0%) 0/50 (0%) SD 0% Total 1/100 (1%)	Total 0/49 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male		Female				
*Testes: Adenoma		2/49 (4%)	0/50 (0%)						
Overall Incidence	Total	2/99 (2.02%)	Mean 2.04%	SD 2.89%					
*Testes: Hemangiosarcoma		0/49 (0%)	0/50 (0%)						
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%					
*Thymus: Sarcoma									
Overall Incidence	Total	0/45 (0%) 0/94 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
*Thymus: Thymoma Benign		0/45 (0%)	1/49 (2%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/94 (1.06%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Thymus: Thymoma: Benign, Mali									
Overall Incidence	Total	0/45 (0%) 1/94 (1.06%)	1/49 (2%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
*Thyroid Gland: Carcinoma									
Overall Incidence	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 29

			Male			Female				
*Thyroid Gland: C-Cell: Adenoma										
		11/45 (24%)	5/50 (10%)			7/45 (16%)	7/50 (14%)			
Overall Incidence	Total	16/95 (16.84%)	Mean 17.22%	SD 10.21%	Total	14/95 (14.74%)	Mean 14.78%	SD 1.1%		
*Thyroid Gland: C-Cell: Carcinoma										
		0/45 (0%)	0/50 (0%)			0/45 (0%)	0/50 (0%)			
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma										
		11/45 (24%)	5/50 (10%)			7/45 (16%)	7/50 (14%)			
Overall Incidence	Total	16/95 (16.84%)	Mean 17.22%	SD 10.21%	Total	14/95 (14.74%)	Mean 14.78%	SD 1.1%		
*Thyroid Gland: Follicular Cell Adenoma										
		1/45 (2%)	3/50 (6%)			1/45 (2%)	3/50 (6%)			
Overall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%		
*Thyroid Gland: Follicular Cell Carcinoma										
		0/45 (0%)	0/50 (0%)			0/45 (0%)	0/50 (0%)			
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma			- (a)				(00)			
		1/45 (2%)	3/50 (6%)	00 0000		1/45 (2%)	3/50 (6%)	05.0050		
Overall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%		

^{*:} 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 Se

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male				Female	
*Urinary Bladder: Carcinoma or Papilloma		0/40 (09/)	4/50 (20/)			0/50 (09/)	4/50 (20%)	
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Urinary Bladder: Papilloma		0/40 (00/)						
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Adenoma								
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Carcinoma						1/50 (2%)	2/50 (69/)	
Overall Incidence					Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%
#Uterus: Granular Cell Tumor Ben	ign							
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Hemangiosarcoma						2/22 (221)	2/22	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

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

Route: GAVAGE

Page: 31

Report Date: 11/11/2014

Vehicle: CORN OIL

Length of Study: CHRONIC

Ma	ale		Female				
#Uterus: Leiomyosarcoma							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Uterus: Malignant Mixed Mullerian Tumor							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%			
#Uterus: Polyp Stromal							
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%			
#Uterus: Sarcoma Stromal							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal or Polyp Stromal							
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%			
#Uterus: Schwannoma Malignant							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 32

			Male			Female			
#Uterus: Squamous Cell Papilloma						(0)	0.50		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Fibrosarcoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Leiomyoma									
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
#Vagina: Polyp									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma									
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 33

Report Date: 11/11/2014

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	052020303	07/18/07	727	50(3)	35(687)	632.7	Green tea extract
					Female		
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green tea extract

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 34
Report Date: 11/11/20

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			Male				Female			
#All Organs: Benign Tumors		26/50 (52%)				38/50 (76%)				
Overall Incidence	Total	26/50 (52%)	Mean 52%	SD 0%	Total	38/50 (76%)	Mean 76%	SD 0%		
#All Organs: Malignant Tumors		12/50 (24%)				16/50 (32%)				
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%		
#All Organs: Malignant and Benign Tu		36/50 (72%)				43/50 (86%)				
Overall Incidence	Total	36/50 (72%)	Mean 72%	SD 0%	Total	43/50 (86%)	Mean 86%	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										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#All Organs: Hemangiosarcoma or He		0/50 (0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 35

			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: Lymphocytic	c, Monocytic, Mo	nonuclear, or Undiffere	ntiated					
		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: Malignant Lymphoma:		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#All Organs: Mesothelioma: Benign,	Malignant, NOS	2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Maligna	nt							
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:								
Osteoma		4/50 (601)						
Osteoma 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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page**: 36

				Male			Female			
#All Organs: Osteosarcoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		2/50	(4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	(470)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		4/50	(00()				0/50 (00/)			
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Carcinoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 37

		Male					Female				
*Adrenal Medulla: Pheochromocytoma Malignant 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: Be	nian Complex	Malignant NOS									
Fileociii oiliocytoilia. Bei	iligii, Collipiex,		(2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	(= / - /	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Blood Vessel: 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%		
*Bone Marrow: Hemangiosarcoma			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteoma											
		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteosarcoma		4/50	(00()				0/50 (00/)				
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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 38

			Male			Female			
#Bone: Osteosarcoma or Osteoma									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma		0/50 (00/)				0/50 (0%)			
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: Glioma 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%	
*Brain: Granular Cell Tumor Benig									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Maligr	nant								
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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 39

			Male			Female			
*Brain: Meningioma Malignant Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Maliç	gnant, NOS								
Overall Incidence	Total	0/50 (09 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Gliom Overall Incidence				SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma		` '				, ,			
*Clitoral/Preputial Gland: Carcinoma or Adenoma		1/50 (29	,			0/49 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Benign		0/50 (09	6)			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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 40

			Male				Female	
*Heart: Schwannoma NOS								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Fibroma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma						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%
#Intestine Small: Jejunum: Leiomyosarcoma		•••••						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unspec Fibroma								
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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 41

			Male				Female					
#Intestine Small: Site Unspecified: Leiomyoma												
•		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Uns Leiomyosarcoma	pecified:											
		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: Adenoma		0/50 (00/)				0/50 (00)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
Overall incidence		, ,				0/50 (0%)	iviean 0%	0% עכ				
*Islets, Pancreatic: Carcinoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Islets, Pancreatic: Carcinoma or Adenoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Kidney: Pelvis and Trans Papilloma	itional Epitheliu											
		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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 42

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		, ,				, ,		SD 0%
*Kidney: Renal Tubule: Liposarcoma		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%
*Liver: Hepatocellular 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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 43

				Male			Female				
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 0/50 (0%) 1/50 (2%)											
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 Carcino	ma, Hepatocellul	ar Adenoma, or	Hepatoblastoma								
•	•		(0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Lung: Alveolar/Bronchiolar Ad	danama				•••••	•••••					
Aiveolai/biolicillolai Ai	denoma	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung:											
Alveolar/Bronchiolar Ca	arcinoma or Alve										
			(0%)		OD		0/50 (0%)		00.007		
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node: Hemangioma											
Ū		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node, Mesenterio						•••••					
Occupation of the second	T-1-1		(0%)	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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 44

			Male			Female				
#Lymph Node, Mesenteric: 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%		
#Mammary Gland: Adenoma										
		0/50 (0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Mammary Gland: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%		
		` '				, ,				
#Mammary Gland: Carcinoma or Adenoma		0/50 (00/)				0/50 (4.00()				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%		
#Mammary Gland: Fibroadenoma										
		0/50 (0%)				11/50 (22%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%		
#Mammary Gland: Fibroma, Fibroadenoma or										
		0/50 (0%)				11/50 (22%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 45

			Male			Female					
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	15/50 (30%) 15/50 (30%)	Mean 30%	SD 0%			
#Mesentery: 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%			
#Mesentery: 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%			
#Mesentery: 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%			
*Nose: Chondroma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Nose: Olfactory Neuroblastoma		0/50 (09/)				0/40 (09/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 46

			Male			Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Oral Cavity (Oral Mucos		nx, Tooth, Gingiva): quamous, or Papilloma								
oquamous cen carcino	oma, i apinoma o	1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Oral Mucosa: Squamous Cell Carcino										
		1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Ovary: Adenoma										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Cystadenoma										
						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor l	Benign									
	-					0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

SD 0%

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Male Female *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Sex Cord Stromal Tumor, Benign 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) *Pancreas: 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% *Pancreas: Carcinoma or Adenoma

SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

Total

0/50

0/50 (0%)

(0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 48

			Male				Female			
*Parathyroid Gland: Adenoma										
		0/47 (0%)				0/47 (0%)				
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Dista Adenoma	alis or Unspeci	fied Site:								
		17/50 (34%)				32/50 (64%)				
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%		
*Pituitary Gland: Pars Dista Carcinoma		fied Site:								
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Dista Carcinoma or Adenoma										
		17/50 (34%)				32/50 (64%)				
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%		
*Pituitary Gland: Pars Inter Adenoma										
		1/50 (2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Pituitary Gland: Pars Inter Carcinoma or Adenoma										
		1/50 (2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 49

			Male				Female	
*Prostate: Adenoma	Total	0/50 (0%)	M 00/	OD 004				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: 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%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Myoepithelioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 50

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% S 0/50 (0%) otal 0/50 (0%) Mean 0% S		
*Salivary Glands: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	()	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (00	Δ			0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%
#Skin: Basal Cell Adenoma		•••••	•••••	•••••	•••••			
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	%) Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign 2/50 (4%)	6)			0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	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: Wistar Han
Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skin: Basal Cell Adenoma. E	Basosquamous T	umor Benign, or Trichoe	epithelioma					
		2/50 (4%)	, p			0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal 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%
#Skin:								
Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	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: Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Adendioma	oma, Basosquamous Tu	mor (benign, maligna	ant or				
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe 6/50 (12%)		ma,		0/50 (0%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		4/50 (631)				0/50 (00/)		
#Skin:	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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 52

			Male				Female	
#Skin: Fibroma, Fibrosarcoma	, Sarcoma, Myxo	oma, Myxosarcoma, or Fi	brous Histiocytoma			0/50 (0%)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	a, Myxosarcoma	, or Fibrous Histiocytoma 0/50 (0%)	3			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hamartoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,				` '		30 0%
#Skin: Hemangiosarcoma		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%
#Skin: Keratoacanthoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 53

			Male		2/50 (4%) Total 2/50 (4%) Mean 4% SD 09 2/50 (4%) Total 2/50 (4%) Mean 4% SD 09 2/50 (4%)			
#Skin: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	` '	Moon 09/	SD 00/
	TOTAL	1/50 (2%)	iviean 2%	3D 0%	ı olal	0/50 (0%)	wiean 0%	טט עס U%
#Skin: Liposarcoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or Sc	hwannoma (m	alignant or NOS) 2/50 (4%)				2/50 (4%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Neurofibrosarcoma, Neur				SD 0%	Total	` ,	Mean 4%	SD 0%
#Skin: Schwannoma Malignant		2/50 (4%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	` '	Mean 4%	SD 0%
#OLE:-								
#Skin: Squamous Cell Carcinom	na	1/50 (2%)				0/50 (0%)		

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

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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

Route: GAVAGE

Page: 54

Report Date: 11/11/2014

Length of Study: CHRONIC

Vehicle: WATER

			Male				Female	
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t or 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%
#Skin: Squamous Cell Papilloma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#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,	Papilloma, S	quamous Cell Carcinom 4/50 (8%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,						0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	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%
Overali ilicidelice	ıvıaı	1/30 (270)	IVICAN ∠70	070 U%	ı Ulal	0/30 (0%)	IVICALI U%	עט עיט

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 55

		Male					Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (29	%)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2		Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (09	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean (% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Fibrosarcoma								
		0/50 (09	,			0/50 (0%)		22. 22/
Overall Incidence	Total	0/50 (0%)	Mean (Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyoma								
		0/50 (09	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean (0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
-		1/50 (29	%)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2	2% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma								
		0/50 (09	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean (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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 56

				Male			Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%					
#Stomach, Forestomach: Squamous Cell Carcinoma 0/50 (0%) 1/50 (2%)												
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 2%	SD 0%			
#Stomach, Forestomach:	er Denillem	· · · · · · · · · · · · · · · · · · ·										
Squamous Cell Carcinoma	or Papillollia	0/50	(0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	` '	Mean 2%	SD 0%			
#Stomach, Forestomach: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%			
#Stomach, Glandular: Fibrosarcoma		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%			
#Stomach, Glandular: Leiomyosarcoma												
·		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Glandular: Sarcoma		0/50	(00()				0/50 (00/)					
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 57

			Male		Total 3/49 (6%) SD 0%			
*Testes: Adenoma								
		2/50 (4%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%				
*Testes: Hemangiosarcoma								
		0/50 (0%)		05 6 0/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Sarcoma		2/12 (221)				2442 (224)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	, ,	Maan Oo/	CD 00/
Overall incidence		0/49 (0%)		3D 0%	TOTAL	0/49 (0%)	wean 0%	3D 0%
*Thymus: Thymoma Benign		2/49 (4%)				3/40 (6%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%		3/49 (6.12%)		
*Thymus: Thymoma: Benign, Malig								
,	, ,	2/49 (4%)				3/49 (6%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	3/49 (6.12%)	Mean 6.12%	SD 0%
*Thyroid Gland: Carcinoma								
	.	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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 58

				Male			Female Total 3/50 (6%) Mean 6% SD 0% 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 4/50 (8%) Mean 8% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0%		
*Thyroid Gland: C-Cell: Adenoma									
Overell Insidence	Tatal		(8%)	Maga 00/	CD 00/	Tatal	(,	Mana 60/	CD 00/
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	ı otal	3/50 (6%)	wean 6%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma									
			(0%)				` '		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		4/50	(8%)				4/50 (8%)		
Overall Incidence	Total	4/50 (8%)	(070)	Mean 8%	SD 0%	Total	` '	Mean 8%	SD 0%
*Thyroid Gland: Follicular Cel Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 2%	SD 0%
		` ,					(,		
*Thyroid Gland: Follicular Cel Carcinoma	l:								
			(0%)				(,		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma			(00/)				4/50 (20/)		
Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	(,	Mean 2%	SD 0%
Overall Incidence	Total	0/50 0/50 (0%)	(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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date: 11/11/2014

Page: 59

Species: RATS
Strain: Wistar Han

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Carcinoma or Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
							······	
*Urinary Bladder: Papilloma								
-		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Uterus:								
Adenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus:								
Carcinoma						3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	SD 0%
#Uterus:								
Granular Cell Tumor Benig	n					2/22 (22/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
						0/50 (0%)		
Overall Incidence					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: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 60

	Male			Female		
#Uterus: Leiomyosarcoma		7 O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 3/50 (6%) Total 3/50 (6%) Mean 6% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%				
Overall Incidence			0/50 (0%)			
#Uterus: Malignant Mixed Mullerian Tumor						
Overall Incidence		Total	` '	Mean 0%	SD 0%	
#Uterus: Polyp Stromal						
Overall Incidence			3/50 (6%)			
#Uterus: Sarcoma Stromal						
Overall Incidence			1/50 (2%)			
#Uterus: Sarcoma Stromal or Polyp Stromal			•••••	•••••		
Overall Incidence		Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	
#Uterus: Schwannoma Malignant						
Overall Incidence		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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 61

			Male				Female	
#Uterus: Squamous Cell Papilloma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Fibrosarcoma					•••••			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Leiomyoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp								
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%
#Zymbal's Gland: Carcinoma or Adenoma								
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: Wistar Han

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: 11/11/2014

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	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	729	50(5)	36(696)	622.2	Metal working fluids (Trim VX)
					Female		
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	731	50(5)	30(681)	391.1	Metal working fluids (Trim VX)

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

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								
Overall Incidence	Total	34/50 (68%) 90/150 (60%)	32/50 (64%) Mean 60%	24/50 (48%) SD 10.58%	Total	33/50 (66%) 117/150 (78%)	42/50 (84%) Mean 78%	42/50 (84%) SD 10.39%
#All Organs: Malignant Tumors								
Overall Incidence	Total	6/50 (12%) 23/150 (15.33%)	13/50 (26%) Mean 15.33%	4/50 (8%) SD 9.45%	Total	17/50 (34%) 41/150 (27.33%)	11/50 (22%) Mean 27.33%	13/50 (26%) SD 6.11%
#All Organs: Malignant and Benign Tu	ımors	36/50 (72%)	37/50 (74%)	26/50 (52%)		40/50 (80%)	43/50 (86%)	47/50 (94%)
Overall Incidence	Total	99/150 (66%)	Mean 66%	SD 12.17%	Total	130/150 (86.67%)	Mean 86.67%	SD 7.02%
#All Organs: Hemangioma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%) 6/150 (4%)	3/50 (6%) Mean 4%	0/50 (0%) SD 3.46%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
#All Organs: Hemangiosarcoma or He	emangioma							
Overall Incidence	Total	4/50 (8%) 8/150 (5.33%)	3/50 (6%) Mean 5.33%	1/50 (2%) SD 3.06%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

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: Histiocytic Sarcoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)			
Overall Incidence To	otal	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%			
#All Organs: Leukemia: Lymphocytic, Monoc	ytic, Mo	nonuclear, or Undifferer	ntiated								
	•	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence To	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
#All Organs: Malignant Lymphoma: Histiocy		0/50 (0%)	0/50 (0%)	1/50 (2%)	Taral	0/50 (0%)	2/50 (4%)	1/50 (2%)			
Overall Incidence To	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%			
#All Organs: Mesothelioma: Benign, Maligna	nt, NOS	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence To	otal	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%			
#All Organs: Mesothelioma: Malignant											
Mesothelioma: Malignant		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Mesothelioma: Malignant	otal	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
•	otal	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	` '	SD 0%			
Mesothelioma: Malignant Overall Incidence #All Organs:	otal	` ,	` ,	` '	Total	` ,	` '	` ,			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

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: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Adenoma								
Overall Incidence	Total	3/50 (6%) 6/150 (4%)	2/50 (4%) Mean 4%	1/50 (2%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign		•••••	•••••					
Overall Incidence	Total	1/49 (2%) 5/149 (3.36%)	4/50 (8%) Mean 3.35%	0/50 (0%) SD 4.16%	Total	0/49 (0%) 1/148 (0.68%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%
Adrenal Medulla: Pheochromocytoma Comple								
Overall Incidence	Total	1/49 (2%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/49 (0%) 0/148 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 66

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Malignant												
•	_	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%				
Adrenal Medulla: Pheochromocytoma: B	enign, Complex	د, Malignant, NOS										
•		2/49 (4%)	4/50 (8%)	0/50 (0%)		0/49 (0%)	2/49 (4%)	0/50 (0%)				
verall Incidence	Total	6/149 (4.03%)	Mean 4.03%	SD 4%	Total	2/148 (1.35%)	Mean 1.36%	SD 2.36%				
Blood Vessel: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Bone Marrow: Hemangiosarcoma												
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
Bone: Osteoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Bone: Osteosarcoma												
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 67

			Male				Female			
#Bone: Osteosarcoma or Osteoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Bone: Sarcoma										
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
*Brain: Glioma										
Overell Institutes	Tatal	0/50 (0%)	2/50 (4%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%		
Brain: Glioma Malignant		2(72 (224)	2(72 (224)	2/72 (221)		2/22 (221)	2/20 (00)	2(72 (224)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Brain: Granular Cell Tumor Benign	ı									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)		
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%		
*Brain: Granular Cell Tumor Maligna	ant									
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		

^{*:} 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

Report Date: 11/11/2014

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Species: RATS
Strain: Wistar Han

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Brain: Meningioma Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mali	gnant, NOS					•••••		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Oligodendroglioma, Gliom	na, or Astrocy	rtoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Schwannoma Benign					••••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Heart: Schwannoma NOS								
	-	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Intestine Small: Jejunum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Unspecit Fibroma								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

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: Site Unspecified: Leiomyoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
fintestine Small: Site Uns Leiomyosarcoma	pecified:												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
Islets, Pancreatic: Adenoma													
	+	0/50 (0%)	0/50 (0%)	5/50 (10%)	-	0/50 (0%)	1/49 (2%)	0/50 (0%)					
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 5.77%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%					
Islets, Pancreatic: Carcinoma													
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%					
Islets, Pancreatic: Carcinoma or Adenoma	ı												
		0/50 (0%)	0/50 (0%)	5/50 (10%)		0/50 (0%)	1/49 (2%)	0/50 (0%)					
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 5.77%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%					
Kidney: Pelvis and Trans Papilloma	itional Epitheli												
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

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: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Kidney: Renal Tubule: Carcinoma								
	.	0/50 (0%)	0/50 (0%)	1/50 (2%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	4/50 (00/)		0/50 (00/)	4/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
		,				1/130 (0.07/0)		
Kidney: Renal Tubule: Lipoma		0/50 (001)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overali incidence		` '				0/150 (0%)		
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female					
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma												
•	•	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
iver: Hepatocellular Carcino		ular Adenoma, or Hepatol										
	а, горилосон	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
Lung: Alveolar/Bronchiolar Ad	denoma	3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lung:		veolar/Bronchiolar Adeno 3/50 (6%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lymph Node: Hemangioma												
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lymph Node, Mesenterio Hemangioma	D :											
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

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	
Lymph Node, Mesenteric: Hemangiosarcoma								
		2/50 (4%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	6/150 (4%)	Mean 4%	SD 4%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	13/150 (8.67%)	Mean 8.67%	SD 1.15%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	6/50 (12%)	8/50 (16%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	19/150 (12.67%)	Mean 12.67%	SD 3.06%
Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	9/50 (18%)	2/50 (4%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	18/150 (12%)	Mean 12%	SD 7.21%
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	11/50 (22%)	6/50 (12%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	24/150 (16%)	Mean 16%	SD 5.29%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Report Date: 11/11/2014

Length of Study: CHRONIC

Vehicle: AIR

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, o	r Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		10/50 (20%)	13/50 (26%)	9/50 (18%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	32/150 (21.33%)	Mean 21.33%	SD 4.16%
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Schwannoma Malignant								
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Olfactory Neuroblastoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Oral Cavity (Oral Mucosa Squamous Cell Carcino		ynx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Oral Cavity (Oral Mucosa		ynx, Tooth, Gingiva): Squamous, or Papilloma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
‡Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ovary: Adenoma						2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Ovary: Cystadenoma								
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Ovary: Granulosa Cell Tumor E	Benign							
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Granulosa Cell Tumor Ma	alignant							
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Ovary: Granulosa Cell Tumor: B								
Overall Incidence					Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
*Ovary: Sex Cord Stromal Tumor								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Pancreas: Adenoma						•••••	•••••	
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (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: Wistar Han

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				
Parathyroid Gland: Adenoma										
		0/44 (0%)	0/43 (0%)	0/39 (0%)		0/39 (0%)	0/47 (0%)	1/42 (2%)		
Overall Incidence	Total	0/126 (0%)	Mean 0%	SD 0%	Total	1/128 (0.78%)	Mean 0.79%	SD 1.37%		
Pituitary Gland: Pars Distali Adenoma										
		14/50 (28%)	16/49 (33%)	14/50 (28%)		19/50 (38%)	35/50 (70%)	34/50 (68%)		
Overall Incidence	Total	44/149 (29.53%)	Mean 29.55%	SD 2.69%	Total	88/150 (58.67%)	Mean 58.67%	SD 17.93%		
Pituitary Gland: Pars Distali Carcinoma	s or Unspec		0/40 (00%)	0/50 (00/)		4/50 (00/)	0/50 (004)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0/49 (0%) Mean 0%	0/50 (0%)	Total	1/50 (2%)	0/50 (0%)	0/50 (0%) SD 1.15%		
	Total	0/149 (0%)		SD 0%	Total	1/150 (0.67%)	Mean 0.67%			
Pituitary Gland: Pars Distali Carcinoma or Adenoma	s or Unspec	cified Site:								
		14/50 (28%)	16/49 (33%)	14/50 (28%)		20/50 (40%)	35/50 (70%)	34/50 (68%)		
Overall Incidence	Total	44/149 (29.53%)	Mean 29.55%	SD 2.69%	Total	89/150 (59.33%)	Mean 59.33%	SD 16.77%		
Pituitary Gland: Pars Interm Adenoma										
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%		
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:									
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%		

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Report Date: 11/11/2014

Vehicle: AIR

Length of Study: CHRONIC

			Male		Female 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%			
*Prostate: Adenoma		1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%				
*Prostate: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%				
*Salivary Glands: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` '
*Salivary Glands: Carcinoma				2/22 (221)		0/50 (00)	(201)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` '	` '
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		` '	` ,	` '
*Salivary Glands: Myoepithelioma		(00)						(00)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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: Wistar Han

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	
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
#Skeletal Muscle: Hemangiosarcoma		2/22 (221)	2/72 (221)	2/22 (221)		2/22 (22)	2/22 (224)	2/22 (221)
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Ba	asosquamous	s Tumor Benign						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Basal Cell Adenoma, Ba	asosquamous 1	Fumor Benign, or Trichoe	oithelioma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma o	r Basosguamo	us Tumor (malignant or N	OS)					
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelid		oma, Basosquamous Tur	` ' ' '					
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Basal or Sq. Cell Carcin		na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	3), Basal Cell Adenon	na,				
Basal or Sq. Cell Carcin		na, Basosq. Tumor (M or E	3), Basal Cell Adenon	na, 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal or Sq. Cell Carcin Adenoma, Papilloma, Sc		na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	3), Basal Cell Adenon ithelioma	•	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	q Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	B), Basal Cell Adenom ithelioma 2/50 (4%)	1/50 (2%)	Total	` ,	()	` '
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence	q Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	B), Basal Cell Adenom ithelioma 2/50 (4%)	1/50 (2%)	Total	` ,	()	` '

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibroma, Fibrosarcoma	, Sarcoma, Myx	koma, Myxosarcoma, or F	ibrous Histiocytoma					
	-	2/50 (4%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
≮Skin: Fibrosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	ı, Myxosarcom	a, or Fibrous Histiocytoma 0/50 (0%)	a 1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Hamartoma		0/50 /00/)		0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
≄Skin: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Keratoacanthoma		4/50 (00/)	4/50 (00/)	4/50 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jveran incluence	ı Ulai	, ,		3D 0%		` '	IVICALI U/0	JD 0/0

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

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								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0 SD 1.15%)%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/150 (0.67%)						
Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	`)%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Neurofibrosarcoma or Sch	wannoma (r	malignant or NOS) 0/50 (0%)	0/50 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma, Neuro	fibroma, or	Schwannoma (benign, ma	alignant or NOS) 0/50 (0%)	0/50 (0)%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	`)%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	`	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: AIR

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			Male				Female	
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,						
Skin: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papilloma	or Papilloma	a						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
∕Skin: Squamous Cell Papilloma	, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthom 1/50 (2%)	a 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papilloma	, Papilloma, e		4/50 /00/	1/FO (20/)		0/50 (09/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Adenoma								
	T	0/50 (0%)	0/50 (0%)	1/50 (2%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

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: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Fibrosarcoma		0/50 (00/)	0/50 /00/	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,				0/150 (0%)	Wear 076	SD 0%
Stomach, Forestomach: Leiomyoma								
O II I I I	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach:								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous							
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Stomach, Glandular: Fibrosarcoma		0/50 (00/)	0/50 (00/)	0/50 (004)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Stomach, Glandular: Leiomyosarcoma									
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Stomach, Glandular: Sarcoma		0/50 /00/	4/50 /000	0/50 (0%)		0/50 (0%)	0/50 (00()	0/50 /00/	
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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: Wistar Han

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				
*Testes: Adenoma									
		6/50 (12%)	2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 6.11%					
*Testes: Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Thymus: Sarcoma									
Overall Incidence	Total	0/41 (0%)	0/40 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/46 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%	
Overall incidence		0/129 (0%)		3D 0%	Total	0/142 (0%)	wiean 0%	טע עא U%	
*Thymus: Thymoma Benign		774	./	2/12 /22/		2(12 (122))	-/ ///	2/42 /4-2/)	
Overall Incidence	Total	3/41 (7%) 7/129 (5.43%)	1/40 (3%) Mean 5.36%	3/48 (6%) SD 2.53%	Total	6/46 (13%) 19/142 (13.38%)	5/48 (10%) Mean 13.38%	8/48 (17%) SD 3.14%	
		1/129 (5.45%)				19/142 (13.30%)		3D 3.14%	
*Thymus: Thymoma: Benign, Malig	ınant, NOS								
		3/41 (7%)	1/40 (3%)	3/48 (6%)		6/46 (13%)	5/48 (10%)	8/48 (17%)	
Overall Incidence	Total	7/129 (5.43%)	Mean 5.36%	SD 2.53%	Total	19/142 (13.38%)	Mean 13.38%	SD 3.14%	
*Thyroid Gland: Carcinoma									
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	1/50 (2%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female				
*Thyroid Gland: C-Cell: Adenoma		5/50 (10%)	7/50 (14%)	3/50 (6%)		4/50 (8%)	3/50 (6%)	7/49 (14%)		
Overall Incidence	Total	15/150 (10%)	Mean 10%	SD 4%	Total	14/149 (9.4%)	Mean 9.43%	SD 4.32%		
*Thyroid Gland: C-Cell: Carcinoma										
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) Mean 0.67%	0/49 (0%) SD 1.15%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma										
Overall Incidence	Total	6/50 (12%) 16/150 (10.67%)	7/50 (14%) Mean 10.67%	3/50 (6%) SD 4.16%	Total	5/50 (10%) 15/149 (10.07%)	3/50 (6%) Mean 10.1%	7/49 (14%) SD 4.14%		
*Thyroid Gland: Follicular Cell Adenoma	:									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%		
*Thyroid Gland: Follicular Cell Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 3/149 (2.01%)	1/50 (2%) Mean 2.01%	1/49 (2%) SD 0.02%		
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:		•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 5/149 (3.36%)	2/50 (4%) Mean 3.35%	1/49 (2%) SD 1.13%		

^{*:} 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: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female			
Urinary Bladder: Carcinoma or Papilloma									
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
rinary Bladder: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Jterus: Adenoma									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
lterus: Carcinoma						3/50 (6%)	1/50 (2%)	1/50 (2%)	
verall Incidence					Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	
Iterus: Granular Cell Tumor Benig	n								
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
lterus: Hemangiosarcoma									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

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

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Leiomyosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Uterus: **Malignant Mixed Mullerian Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 2/50 (4%)5/50 (10%) 6/50 (12%) **Overall Incidence** Total 13/150 (8.67%) Mean 8.67% SD 4.16% #Uterus: Sarcoma Stromal 1/50 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% #Uterus: Sarcoma Stromal or Polyp Stromal 3/50 (6%)6/50 (12%) 7/50 (14%) **Overall Incidence** Total 16/150 (10.67%) Mean 10.67% SD 4.16% **#Uterus: Schwannoma Malignant** 0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** 2/150 (1.33%) Mean 1.33% SD 2.31% Total

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Female					
tUterus: Squamous Cell Papilloma							(20)		2/22 (22)
Overall Incidence						Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Vagina: Fibrosarcoma									
verall Incidence						Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Vagina: Leiomyoma									
verall Incidence						Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
/agina: Polyp			•••••						
verall Incidence						Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Zymbal's Gland: Carcinoma			•••••						
verall incidence	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 SD 2%	(2%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Zymbal's Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 SD 2%	(2%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied