

NTP Historical Controls Report

All Routes and Vehicles

Wistar Han RATS

November 2014

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male M1 M2 M3 M4 M5 Female F1 F2 F3 F4 F5

the data would be shown as:

	Male			Female	
M1	M2	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.

Version: Nov2014 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: ALL ROUTES Vehicle: ALL VEHICLES

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 Columbus Laboratory	052020303	07/18/07	727	50(3)	35(687)	632.7	Green tea extract			
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)			
Southern Research Institute	052020903	08/26/08	729	49(3)	36(671)	673.4	Pentabromodiphenyl oxide (technical) (DE 71)			
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A			
					Female					
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide			
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green tea extract			
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)			
Southern Research Institute	052020903	08/26/08	732	50(5)	37(678)	389.6	Pentabromodiphenyl oxide (technical) (DE 71)			
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A			

Version:	Nov2014

Species: RATS

Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 4 Report Date: 11/11/2014

			Male				Female	
#All Organs: Benign Tumors								
		34/50 (68%)	26/50 (52%)	32/50 (64%)		33/50 (66%)	38/50 (76%)	42/50 (84%)
N	Tatal	24/50 (48%)	33/49 (67%)	30/50 (60%)	T . (.)	42/50 (84%)	37/50 (74%)	38/50 (76%)
Overall Incidence	Total	179/299 (59.87%)	Mean 59.89%	SD 8.27%	Total	230/300 (76.67%)	Mean 76.67%	SD 6.77%
¢All Organs: Malignant Tumors								
		6/50 (12%)	12/50 (24%)	13/50 (26%)		17/50 (34%)	16/50 (32%)	11/50 (22%)
		4/50 (8%)	13/49 (27%)	8/50 (16%)		13/50 (26%)	10/50 (20%)	10/50 (20%)
Overall Incidence	Total	56/299 (18.73%)	Mean 18.76%	SD 7.87%	Total	77/300 (25.67%)	Mean 25.67%	SD 6.12%
#All Organs: Malignant and Benign T		36/50 (72%) 26/50 (52%)	36/50 (72%) 36/49 (73%)	37/50 (74%) 34/50 (68%)		40/50 (80%) 47/50 (94%)	43/50 (86%) 40/50 (80%)	43/50 (86%) 40/50 (80%)
Overall Incidence	Total	205/299 (68.56%)	Mean 68.58%	SD 8.39%	Total	253/300 (84.33%)	Mean 84.33%	SD 5.57%
All Organs: Hemangioma		1/50 (2%)	0/50 (0%/)				0/50 (0%)	0/50 (0%)
		1/50 (2%) 1/50 (2%)	0/50 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		3/50 (6%) 0/50 (0%)	0/50 (0%) 8/49 (16%)	3/50 (6%) 3/50 (6%)		1/50 (2%) 0/50 (0%)	2/50 (4%) 2/50 (4%)	1/50 (2%) 2/50 (4%)
				0,00 (0,0)		0,00 (0,0)		

*: Denominator is number of animals with tissues examined microscopically

Version:	Nov2014

Species: RATS

Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 5 Report Date: 11/11/2014

			Male				Female	
¥All Organs: Hemangiosarcoma or ∣	Hemangioma							
		4/50 (8%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
		1/50 (2%)	9/49 (18%)	4/50 (8%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	21/299 (7.02%)	Mean 7.06%	SD 6.42%	Total	8/300 (2.67%)	Mean 2.67%	SD 1.63%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#All Organs: Leukemia: Lymphocyt	tic, Monocytic, M	Iononuclear, or Undiffer 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	t ic, Monocytic, M Total	•		0/50 (0%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Leukemia: Lymphocyt Overall Incidence #All Organs:	Total	1/50 (2%) 0/50 (0%) 3/299 (1%)	0/50 (0%) 1/49 (2%) Mean 1.01%	1/50 (2%) SD 1.1%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Leukemia: Lymphocyt Overall Incidence #All Organs:	Total	1/50 (2%) 0/50 (0%) 3/299 (1%) mphocytic, Mixed, NOS, 0/50 (0%)	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel 0/50 (0%)	1/50 (2%) SD 1.1% I Type 0/50 (0%)	Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%)
Leukemia: Lymphocyt Overall Incidence #All Organs: Malignant Lymphoma:	Total	1/50 (2%) 0/50 (0%) 3/299 (1%) nphocytic, Mixed, NOS,	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel	1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%)
Leukemia: Lymphocyt Overall Incidence #All Organs:	Total	1/50 (2%) 0/50 (0%) 3/299 (1%) mphocytic, Mixed, NOS, 0/50 (0%)	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel 0/50 (0%)	1/50 (2%) SD 1.1% I Type 0/50 (0%)	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%) SD 0% 2/50 (4%)
Leukemia: Lymphocyt Overall Incidence #All Organs: Malignant Lymphoma:	Total : Histiocytic, Lyn Total	1/50 (2%) 0/50 (0%) 3/299 (1%) mphocytic, Mixed, NOS, 0/50 (0%) 1/50 (2%) 1/299 (0.33%)	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel 0/50 (0%) 0/49 (0%)	1/50 (2%) SD 1.1% I Type 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%)
Leukemia: Lymphocyt Overall Incidence #All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Total : Histiocytic, Lyn Total	1/50 (2%) 0/50 (0%) 3/299 (1%) mphocytic, Mixed, NOS, 0/50 (0%) 1/50 (2%) 1/299 (0.33%) S 0/50 (0%)	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel 0/50 (0%) 0/49 (0%)	1/50 (2%) SD 1.1% I Type 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%)
Leukemia: Lymphocyt Overall Incidence #All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Total : Histiocytic, Lyn Total	1/50 (2%) 0/50 (0%) 3/299 (1%) mphocytic, Mixed, NOS, 0/50 (0%) 1/50 (2%) 1/299 (0.33%)	0/50 (0%) 1/49 (2%) Mean 1.01% or Undifferentiated Cel 0/50 (0%) 0/49 (0%) Mean 0.33%	1/50 (2%) SD 1.1% I Type 0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%) Mean 1.33%	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%) SD 1.63%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 6 Report Date: 11/11/2014

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/49 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/299 (0.33%)						
#All Organs: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
		()		5D 1.05%	10tai	1/300 (0.33%)		3D 0.02%
All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/299 (1%)	0/49 (0%) Mean 1%	0/50 (0%) SD 1.67%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
		3/299 (170)				1/300 (0.33%)		3D 0.02 //
Adrenal Cortex: Adenoma								
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/50 (2%) 7/299 (2.34%)	0/49 (0%) Mean 2.33%	0/50 (0%) SD 2.34%	Total	0/50 (0%) 4/300 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.63%
		· ,				()		

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 7 Report Date: 11/11/2014

			Male				Female	
Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/299 (0.67%)	1/49 (2%) Mean 0.67%	0/50 (0%) SD 1.04%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%
Adrenal Medulla: Pheochromocytoma Be								
		1/49 (2%)	1/50 (2%)	4/50 (8%)		0/49 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	0/50 (0%) 6/297 (2.02%)	0/49 (0%) Mean 2.01%	0/49 (0%) SD 3.1%	Total	0/50 (0%) 5/297 (1.68%)	1/50 (2%) Mean 1.69%	2/49 (4%) SD 1.53%
Adrenal Medulla: Pheochromocytoma Co	·	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.34%	SD 0.83%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%
Adrenal Medulla: Pheochromocytoma M	lalignant	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/49 (2%)
		0/50 (0%)	1/49 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.34%	SD 0.83%	Total	1/297 (0.34%)	Mean 0.34%	SD 0.83%
Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	x, Malignant, NOS						
		2/49 (4%) 0/50 (0%)	1/50 (2%) 1/49 (2%)	4/50 (8%) 0/49 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	2/49 (4%) 2/49 (4%)
Overall Incidence	Total	8/297 (2.69%)	Mean 2.69%	SD 3.02%	Total	7/297 (2.36%)	Mean 2.36%	SD 1.99%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 8 Report Date: 11/11/2014

			Male				Female	
fBlood Vessel: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	1/50 (2%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Bone Marrow: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T	0/50 (0%)	0/49 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T	0/50 (0%)	0/49 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
/Bone: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N U I !	T . (.)	0/50 (0%)	0/49 (0%)	0/50 (0%)	T . (.)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 9 Report Date: 11/11/2014

			Male				Female	
#Bone: Sarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Glioma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.63%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Glioma Malignant								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Be	nign							
	•	1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/50 (0%) 5/299 (1.67%)	1/49 (2%) Mean 1.67%	1/50 (2%) SD 1.51%	Total	0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.67%
		5/299 (1.07 /0)				3/300 (178)		
Brain: Granular Cell Tumor Ma	lignant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 10 Report Date: 11/11/2014

			Male				Female				
*Brain: Meningioma Malignant 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)											
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
		· · · ·				()					
Brain: Meningioma: Benign, Mali	ignant, NOS										
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%			
Brain: Oligodendroglioma, Glion Overall Incidence	Total	/toma 0/50 (0%) 0/50 (0%) 2/299 (0.67%)	1/50 (2%) 1/49 (2%) Mean 0.67%	0/50 (0%) 0/50 (0%) SD 1.04%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%			
Clitoral/Preputial Gland: Carcinoma				- / /							
		0/50 (0%) 0/49 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/298 (0%)	Mean 0%	SD 0%			
	10tai	2,230 (0.07.70)				0/200 (0/0)					
Clitoral/Preputial Gland: Carcinoma or Adenoma											
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/298 (0%)	Mean 0%	SD 0%			

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 11 Report Date: 11/11/2014

			Male				Female	
Heart: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Heart: Schwannoma NOS								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	1/49 (2%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
fIntestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 12 Report Date: 11/11/2014

			Male				Female	
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Site Unsp Fibroma	ecified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Unsp Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Islets, Pancreatic: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		5/50 (10%)	4/49 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/299 (3.34%)	Mean 3.36%	SD 4.54%	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 13 Report Date: 11/11/2014

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/49 (4%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%	Total	0/299 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		5/50 (10%)	6/49 (12%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/299 (4.01%)	Mean 4.04%	SD 5.59%	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%
Kidney: Pelvis and Transitic Papilloma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
	T	0/50 (0%)	0/49 (0%)	0/50 (0%)	T ()	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 14 Report Date: 11/11/2014

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
	T ()	1/50 (2%)	0/49 (0%)	0/50 (0%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 2.47%	Total	6/300 (2%)	Mean 2%	SD 2.19%
Liver: Hepatocellular Carcinoma d	or Hepatoce	ellular Adenoma						
-	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 2.47%	Total	6/300 (2%)	Mean 2%	SD 2.19%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2014 Contract/Lab: All Laboratories Species: RATS Route: ALL ROUTES Strain: Wistar Han Vehicle: ALL VEHICLES Length of Study: CHRONIC Male *Liver:

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%) (0%) 1/50 (2%) 3/49 (6%) 0/50 0/50 (0%) 3/50 (6%) 1/50 (2%) **Overall Incidence** Total 4/299 (1.34%) Mean 1.35% SD 2.47% Total 6/300 (2%) Mean 2% SD 2.19% *Lung: Alveolar/Bronchiolar Adenoma (6%) (0%) 3/50 0/50 (0%) 1/50 (2%) 0/50 0/50 (0%) 0/50 (0%) (0%) 0/50 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Overall Incidence** Total 4/299 (1.34%) Mean 1.33% SD 2.42% Total 0/300 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 3/50 (6%) 0/50 (0%) 1/50 (2%) 0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Overall Incidence** Total 4/299 (1.34%) Mean 1.33% SD 2.42% 0/300 (0%) Mean 0% SD 0% Total #Lymph Node: Hemangioma 0/50 0/50 (0%) 0/50 (0%) (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Lymph Node, Mesenteric: Hemangioma 1/50 (2%)0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/49 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Overall Incidence** Total 3/299 (1%) Mean 1.01% SD 1.1% Total 0/300 (0%) Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Female

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 16 Report Date: 11/11/2014

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 13/299 (4.35%)	7/49 (14%) Mean 4.38%	1/50 (2%) SD 5.38%	Total	0/50 (0%) 5/300 (1.67%)	2/50 (4%) Mean 1.67%	1/50 (2%) SD 1.51%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	12/300 (4%)	Mean 4%	SD 3.58%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	6/50 (12%)	4/50 (8%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	21/300 (7%)	Mean 7%	SD 4.15%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		5/50 (10%)	8/50 (16%)	6/50 (12%)
0	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	T . (.)	8/50 (16%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	32/300 (10.67%)	Mean 10.67%	SD 5.32%
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	11/50 (22%)	9/50 (18%)
• ••• ••		0/50 (0%)	0/49 (0%)	1/50 (2%)	-	2/50 (4%)	9/50 (18%)	8/50 (16%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	46/300 (15.33%)	Mean 15.33%	SD 6.15%

*: Denominator is number of animals with tissues examined microscopically

Version:	Nov2014

Species: RATS

Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 17 Report Date: 11/11/2014

			Male				Female	
Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	11/50 (22%)	11/50 (22%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		6/50 (12%)	9/50 (18%)	12/50 (24%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	56/300 (18.67%)	Mean 18.67%	SD 4.84%
Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, o	r Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		10/50 (20%)	15/50 (30%)	13/50 (26%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		9/50 (18%)	10/50 (20%)	12/50 (24%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	69/300 (23%)	Mean 23%	SD 4.52%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignant	:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 18 Report Date: 11/11/2014

			Male				Female	
Nose: Chondroma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 1/299 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Nose: Olfactory Neuroblasto								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		rynx, Tooth, Gingiva): 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	rynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		1/299 (0.3376)			1 Utai	1/300 (0.3376)		3D 0.02 <i>%</i>
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2014 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: ALL ROUTES Vehicle: ALL VEHICLES		Page: 19 Report Date: 11/11/2014			
	Male		Female			
*Ovary: Adenoma						
		()	0/50(0%)0/50(0%)0/50(0%)0/50(0%)			
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.63%			
*Ovary: Cystadenoma						
Cystadenoma		1/50 (2%)	0/50 (0%) 0/50 (0%)			
			0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%			
*Ovary: Granulosa Cell Tumor Benign						
5			0/50 (0%) 1/50 (2%)			
		0/50 (0%)	1/50 (2%) 0/50 (0%)			
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.03%			
*Ovary: Granulosa Cell Tumor Malignant						
Granulosa Cen Tumor Manghant		0/50 (0%)	0/50 (0%) 0/50 (0%)			
			1/50 (2%) 1/50 (2%)			
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.1%			
*Ovary:						
Granulosa Cell Tumor: Benign, Malignant, NOS			0/50(0%)1/50(2%)2/50(4%)1/50(2%)			
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67% SD 1.51%			
*: Denominator is number of animals with tissues examined micros	scopically					

Version: Nov2014 Contract/Lab: All Laborator Species: RATS Strain: Wistar Han Length of Study: CHRONIC			Tumor Incider	logy Data Management nce for Selected Control A Route: ALL ROUTES Vehicle: ALL VEHICLES	Animal Groups		Page: 20 Report Da	te: 11/11/2014
			Male				Female	
*Ovary: Sex Cord Stromal Tumo	r, Benign							
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
*Ovary:								
Tubulostromal Adenoma	3					2/50 (4%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
*Pancreas: Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/46 (2%)	1/50 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	4/296 (1.35%)	Mean 1.36%	SD 1.06%	Total	0/299 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	1/46 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/296 (1.35%)	Mean 1.36%	SD 1.06%	Total	0/299 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/44 (0%)	0/47 (0%)	0/43 (0%)		0/39 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	0/39 (0%) 2/265 (0.75%)	2/47 (4%) Mean 0.71%	0/45 (0%) SD 1.74%	Total	1/42 (2%) 2/272 (0.74%)	1/49 (2%) Mean 0.74%	0/48 (0%) SD 1.15%

Version:	Nov2014

Species: RATS

Strain: Wistar Han Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 21 Report Date: 11/11/2014

			Male				Female	
Pituitary Gland: Pars Dis Adenoma	stalis or Unspe	cified Site:						
		14/50 (28%)	17/50 (34%)	16/49 (33%)		19/50 (38%)	32/50 (64%)	35/50 (70%)
Overall Incidence	Total	14/50 (28%) 101/298 (33.89%)	19/49 (39%) Mean 33.9%	21/50 (42%) SD 5.67%	Total	34/50 (68%) 164/300 (54.67%)	23/50 (46%) Mean 54.67%	21/50 (42%) SD 14.24%
Pituitary Gland: Pars Dis Carcinoma		cified Site:						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Carcinoma or Adenoma	a	14/50 (28%) 14/50 (28%)	17/50 (34%) 19/49 (39%)	16/49 (33%) 21/50 (42%)		20/50 (40%) 34/50 (68%)	32/50 (64%) 23/50 (46%)	35/50 (70%) 21/50 (42%)
Carcinoma or Adenoma	a Total	14/50 (28%)	19/49 (39%) Mean 33.9%	()	Total	34/50 (68%) 165/300 (55%)	()	()
Carcinoma or Adenoma	a Total	14/50 (28%) 14/50 (28%) 101/298 (33.89%)	19/49 (39%) Mean 33.9%	21/50 (42%) SD 5.67%		34/50 (68%) 165/300 (55%)	23/50 (46%)	21/50 (42%)
Carcinoma or Adenoma Overall Incidence Pituitary Gland: Pars Inte	a Total	14/50 (28%) 14/50 (28%) 101/298 (33.89%) 1/50 (2%)	19/49 (39%) Mean 33.9% 1/50 (2%)	21/50 (42%) SD 5.67% 2/49 (4%)		34/50 (68%) 165/300 (55%) 0/50 (0%)	23/50 (46%) Mean 55% 2/50 (4%)	21/50 (42%) SD 13.78% 1/50 (2%)
Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Inte Adenoma Overall Incidence	a Total ermedia: Total	14/50 (28%) 14/50 (28%) 101/298 (33.89%) 1/50 (2%) 1/50 (2%) 7/298 (2.35%)	19/49 (39%) Mean 33.9%	21/50 (42%) SD 5.67%		34/50 (68%) 165/300 (55%)	23/50 (46%) Mean 55%	21/50 (42%) SD 13.78%
Overall Incidence *Pituitary Gland: Pars Inte	a Total ermedia: Total ermedia:	14/50 (28%) 14/50 (28%) 101/298 (33.89%) 1/50 (2%) 1/50 (2%) 7/298 (2.35%)	19/49 (39%) Mean 33.9% 1/50 (2%) 0/49 (0%)	21/50 (42%) SD 5.67% 2/49 (4%) 2/50 (4%)		34/50 (68%) 165/300 (55%) 0/50 (0%) 1/50 (2%)	23/50 (46%) Mean 55% 2/50 (4%) 1/50 (2%)	21/50 (42%) SD 13.78% 1/50 (2%) 4/50 (8%)
Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Inte Adenoma Overall Incidence *Pituitary Gland: Pars Inte	a Total ermedia: Total ermedia:	14/50 (28%) 14/50 (28%) 101/298 (33.89%) 1/50 (2%) 1/50 (2%) 7/298 (2.35%)	19/49 (39%) Mean 33.9% 1/50 (2%) 0/49 (0%)	21/50 (42%) SD 5.67% 2/49 (4%) 2/50 (4%)		34/50 (68%) 165/300 (55%) 0/50 (0%) 1/50 (2%)	23/50 (46%) Mean 55% 2/50 (4%) 1/50 (2%)	21/50 (42%) SD 13.78% 1/50 (2%) 4/50 (8%)

*: Denominator is number of animals with tissues examined microscopically

Version:	Nov2014

Species: RATS

Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 22 Report Date: 11/11/2014

			Male				Female	
*Prostate: Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/50 (0%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.03%				
Prostate: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)				
• ••• ••	-	0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%				
Salivary Glands: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/46 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.36%	SD 0.89%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
	-	0/50 (0%)	0/46 (0%)	0/50 (0%)	-	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
0	Tatal	0/50 (0%)	1/46 (2%)	0/50 (0%)	T - (- 1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.36%	SD 0.89%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

Version:	Nov2014
----------	---------

Species: RATS

Strain: Wistar Han Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/46 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	2/296 (0.68%)	Mean 0.67%	SD 1.03%	Total	0/299 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	1/50 (2%)				
Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%				
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/50 (0%) 1/299 (0.33%)	1/49 (2%) Mean 0.34%	0/50 (0%) SD 0.83%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	·····						
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	()	()	()	Total	· · /	()	0/50 (0%) SD 0%
-	Total Total Total Total	0/50 (0%) Total 2/296 (0.68%) 0/50 (0%) 0/50 (0%) Total 1/296 (0.34%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/299 (0.33%) 0/50 (0%) 0/50 (0%) 0/5	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0/50 (0%) 0/46 (0%) 1/50 (2%) 0/50 (0%) Total 2/296 (0.68%) Mean 0.67% SD 1.03% Total 0/299 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/296 (0.34%) Mean 0.33% SD 0.82% Total 0/299 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/299 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/299 (0%) Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/50 (0%) Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 24 Report Date: 11/11/2014

			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
skin: Basal Cell Adenoma or B	asosquamous	s Tumor Benign						
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 5/299 (1.67%)	2/50 (4%) 1/49 (2%) Mean 1.67%	0/50 (0%) 2/50 (4%) SD 1.97%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Skin:								
Basal Cell Carcinoma						0/50 (0%)		0/50 (0%)
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		()	0/50 (0%)	()
	Total	0/50 (0%)	0/49 (0%)	1/50 (2%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	()	()	()	Total	()	()	()
Overall Incidence		0/50 (0%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence #Skin:		0/50 (0%) 2/299 (0.67%) us Tumor (malignant or N 0/50 (0%)	0/49 (0%) Mean 0.67% IOS) 0/50 (0%)	1/50 (2%) SD 1.03% 1/50 (2%)	Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)
Overall Incidence #Skin:		0/50 (0%) 2/299 (0.67%) us Tumor (malignant or N	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

			Toxicol	ogy Data Management	System	Page: 25		
Contract/Lab: All Laboratories	;		Tumor Incider	nce for Selected Control A	nimal Groups		Report Dat	te: 11/11/2014
pecies: RATS								
Strain: Wistar Han				Vehicle: ALL VEHICLES				
ength of Study: CHRONIC								
			Male				Female	
/Skin:								
Basal Cell Carcinoma, Basa NOS), or Trichoepithelioma	al Cell Aden a	ioma, Basosquamous Tur	nor (benign, maligna	nt or				
<i>,,</i>		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.79%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin:								
Basal or Sq. Cell Carcinom	a. Carcinom	na. Basoso. Tumor (M or F	3). Basal Cell Adenon	na.				
Adenoma, Papilloma, Sq Pa	apilloma, Ke	eratoacanthoma, Trichoep	oithelioma	,				
			0/50 (400/)	0/50 (40/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	6/50 (12%)	2/50 (4%)		()	()	()
		1/50 (2%)	3/49 (6%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 20/299 (6.69%)	3/49 (6%) Mean 6.69%	7/50 (14%) SD 5.16%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall Incidence		1/50 (2%) 20/299 (6.69%)	3/49 (6%) Mean 6.69%	7/50 (14%) SD 5.16%		0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall Incidence		1/50 (2%) 20/299 (6.69%)	3/49 (6%) Mean 6.69%	7/50 (14%) SD 5.16%		0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall Incidence Skin:		1/50 (2%) 20/299 (6.69%)	3/49 (6%) Mean 6.69%	7/50 (14%) SD 5.16%		0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
overall Incidence Skin:		1/50 (2%) 20/299 (6.69%)	3/49	7/50 (14%) SD 5.16%		0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall Incidence Skin: Fibroma Overall Incidence	Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27%	Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence	Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27%	Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence Skin:	Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27%	Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence	Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27%	Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence Skin:	Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27%	Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63%
Overall Incidence Skin: Fibroma Overall Incidence Skin: Fibroma, Fibrosarcoma, Sa	Total arcoma, Myx Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi 2/50 (4%) 1/50 (2%) 7/299 (2.34%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01% ibrous Histiocytoma 1/50 (2%) 1/49 (2%) Mean 2.34%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27% 2/50 (4%) 0/50 (0%) SD 1.5%	Total Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%) 2/50 (4%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence Skin: Fibroma, Fibrosarcoma, Sa	Total arcoma, Myx Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi 2/50 (4%) 1/50 (2%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01% ibrous Histiocytoma 1/50 (2%) 1/49 (2%) Mean 2.34%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27% 2/50 (4%) 0/50 (0%)	Total Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%) 2/50 (4%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence Skin: Fibroma, Fibrosarcoma, Sa	Total arcoma, Myx Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi 2/50 (4%) 1/50 (2%) 7/299 (2.34%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01% ibrous Histiocytoma 1/50 (2%) 1/49 (2%) Mean 2.34%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27% 2/50 (4%) 0/50 (0%) SD 1.5%	Total Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%) 2/50 (4%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma, Fibrosarcoma, Sa Overall Incidence	Total arcoma, Myx Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi 2/50 (4%) 1/50 (2%) 7/299 (2.34%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01% ibrous Histiocytoma 1/50 (2%) 1/49 (2%) Mean 2.34%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27% 2/50 (4%) 0/50 (0%) SD 1.5%	Total Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%) 2/50 (4%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Fibroma Overall Incidence Skin: Fibroma, Fibrosarcoma, Sa Overall Incidence	Total arcoma, Myx Total	1/50 (2%) 20/299 (6.69%) 2/50 (4%) 1/50 (2%) 6/299 (2.01%) xoma, Myxosarcoma, or Fi 2/50 (4%) 1/50 (2%) 7/299 (2.34%)	3/49 (6%) Mean 6.69% 1/50 (2%) 1/49 (2%) Mean 2.01% ibrous Histiocytoma 1/50 (2%) 1/49 (2%) Mean 2.34%	7/50 (14%) SD 5.16% 1/50 (2%) 0/50 (0%) SD 1.27% 2/50 (4%) 0/50 (0%) SD 1.5%	Total Total	0/50 (0%) 1/300 (0.33%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%) 2/50 (4%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%) SD 1.63%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2014 Contract/Lab: All Laboratorie Species: RATS Strain: Wistar Han Length of Study: CHRONIC		Toxicology Data Mana Tumor Incidence for Selected Route: ALL R Vehicle: ALL Vi					ted Control A	Control Animal Groups DUTES				Page: 26 Report Da	te: 11/11/20)14
					Male						F	emale		
#Skin: Fibrosarcoma, Sarcoma,	Muxosarcom	a or Eibrous Hi	stiogytom											
Fibrosarconia, Sarconia,	wyxosarcoma	0/50 0/50	(0%) (0%)	0/50 0/49	(0%) (0%)	1/50 0/50	(2%) (0%)		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
Overall Incidence	Total	1/299 (0.33	. ,	Mean 0	· · ·	SD 0.829	· · ·	Total	0/300 (()		an 0%	SD	
#Skin: Hamartoma														
hamartonia		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/50 1/299 (0.33	(0%) 3%)	0/49 Mean 0	(0%)) 33%	0/50 SD 0.829	(0%) %	Total	0/50 0/300 ((0%) (0%)	0/50 Mea	(0%) an 0%	0/50 SD	(0%) 0%
			,											
#Skin: Hemangiosarcoma														
Temangrooaroonna		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/299 (0%	,	Mean	0%	SD 0%		Total	1/300 (0.	33%)	Mean	0.33%	SD 0	.82%
#Skin: Keratoacanthoma														
		1/50 1/50	(2%) (2%)	2/50 2/49	(4%) (4%)	1/50 4/50	(2%) (8%)		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	11/299 (3.68	· · ·	Z/49 Mean 3	· · ·	4/50 SD 2.349	()	Total	0/300 (()		(0%) an 0%	0/50 SD	(0%) 0%
#Skin: Lipoma														
		0/50 0/50	(0%) (0%)	1/50 0/49	(2%)	1/50	(2%)		0/50 0/50	(0%)	0/50 0/50	(0%)	0/50 0/50	(0%)
Overall Incidence	Total	0/50 2/299 (0.67	()	0/49 Mean 0	(0%)	0/50 SD 1.039	(0%) %	Total	0/300 ((0%)		(0%) an 0%	0/50 SD	(0%)

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 27 Report Date: 11/11/2014

			Male				Female	
≭Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		0/299 (076)				()		
Skin: Neurofibrosarcoma or	Schwannoma (r	nalignant or NOS)						
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 2.07%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
	euronbronia, or	Schwannoma (benign, ma		0/50 (09/)		0/50 (09/)	2/50 (49/)	0/50 (0%)
	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%)	2/50 (4%) 0/49 (0%) Mean 1.33%	0/50 (0%) 2/50 (4%) SD 2.07%	Total	0/50 (0%) 0/50 (0%) 2/300 (0.67%)	2/50 (4%) 0/50 (0%) Mean 0.67%	0/50 (0%) 0/50 (0%) SD 1.63%
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%)	2/50 (4%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Dverall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%)	2/50 (4%) SD 2.07% 0/50 (0%)	Total	0/50 (0%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%)	0/50 (0%) SD 1.63% 0/50 (0%)
Overall Incidence #Skin: Schwannoma Malignar	Total nt	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%)	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%)		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%)	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence #Skin: Schwannoma Malignar	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%)	2/50 (4%) SD 2.07% 0/50 (0%)	Total Total	0/50 (0%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%)	0/50 (0%) SD 1.63% 0/50 (0%)
Dverall Incidence #Skin: Schwannoma Malignar Dverall Incidence	Total nt Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%)	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%)		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%)	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence #Skin: Schwannoma Malignar Overall Incidence #Skin:	Total nt Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%) Mean 1.33%	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%) SD 2.07% 0/50 (0%)		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%) Mean 0.67% 0/50 (0%)	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%) SD 1.63% 0/50 (0%)
Overall Incidence #Skin: Schwannoma Malignar Overall Incidence #Skin:	Total nt Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%) 4/299 (1.34%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%) Mean 1.33%	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%) SD 2.07%		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%) SD 1.63%

*: Denominator is number of animals with tissues examined microscopically

contract/Lab: All Laborator				nogy Data management			1 age. 20	
	ies		Tumor Incide	nce for Selected Control	Animal Groups		Report Da	te: 11/11/2014
Species: RATS				Route: ALL ROUTES			-	
Strain: Wistar Han				Vehicle: ALL VEHICLES	5			
Length of Study: CHRONIC	2							
Length of Olday. Of Month	5							
			Male				Female	
#Skin: Squamous Cell Carcinor or Carcinoma	ma, Basal Cell	Carcinoma, Basosqua	imous Tumor (malignan	t or NOS),				
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a							
		0/50 (0%)	· · ·	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	()	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a or Papilloma	1						
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	()	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
				CD 1 020/	Total	0/300 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	10tai	0,000 (0,0)		
#Skin:		·····						
		·····	oma or Keratoacanthom		10(2)	0/50 (0%)	0/50 (0%)	0/50 (0%)
#Skin:		Squamous Cell Carcin	oma or Keratoacanthom 4/50 (8%)	 1a		·····		0/50 (0%) 0/50 (0%)

5/50 (10%)

SD 3.2%

0/50

Total

0/300 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Toxicology Data Management System

Page: 28

*: Denominator is number of animals with tissues examined microscopically

Total

1/50

13/299 (4.35%)

(2%)

2/49

Mean 4.35%

(4%)

Denominator is number of animals marrangiad

#: Denominator is number of animals necropsied

Overall Incidence

Version: Nov2014

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 29 Report Date: 11/11/2014

			Male				Female	
∕Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						0/000 (0/0)		
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/299 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2/299 (0.07 %)				0/300 (0 %)		
Spleen: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T	0/50 (0%)	1/47 (2%)	1/50 (2%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/297 (0.67%)	Mean 0.69%	SD 1.07%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	Tatal	0/50 (0%)	1/49 (2%)	0/50 (0%)	T - 4 - 1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyoma								
-		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 30 Report Date: 11/11/2014

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Stomach, Forestomach: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		()				()		
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#Stomach, Forestomach: Squamous Cell Carcinoma		aa Squamous 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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	0/50 (0%)	1/49 (2%)	0/50 (0%) SD 0.83%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jverall Incluence		1/299 (0.33%)	Mean 0.34%		Total	0/300 (0%)		

*: Denominator is number of animals with tissues examined microscopically

Version:	Nov2014

Species: RATS

Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES

Page: 31 Report Date: 11/11/2014

			Male				Female	
≭Stomach, Glandular: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N	T . (.)	0/50 (0%)	1/49 (2%)	0/50 (0%)	T - (- 1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		6/50 (12%)	2/50 (4%)	2/50 (4%)				
Nuevell In eiden ee	Tatal	0/50 (0%)	2/49 (4%)	0/50 (0%)				
Overall Incidence	Total	12/299 (4.01%)	Mean 4.01%	SD 4.38%				
Testes: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Numeri Instalan as	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				

*: Denominator is number of animals with tissues examined microscopically

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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 32 Report Date: 11/11/2014

			Male				Female	
'Thymus: Sarcoma								
		0/41 (0%)	0/49 (0%)	0/40 (0%)		0/46 (0%)	0/49 (0%)	0/48 (0%)
		0/48 (0%)	0/45 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/272 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.33%	SD 0.82%
Thymus: Thymoma Benign								
-		3/41 (7%)	2/49 (4%)	1/40 (3%)		6/46 (13%)	3/49 (6%)	5/48 (10%)
		3/48 (6%)	0/45 (0%)	1/49 (2%)		8/48 (17%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	10/272 (3.68%)	Mean 3.7%	SD 2.74%	Total	23/291 (7.9%)	Mean 8.04%	SD 6.48%
'Thymus: Thymoma: Benign, Malig								
		3/41 (7%)	2/49 (4%)	1/40 (3%)		6/46 (13%)	3/49 (6%)	5/48 (10%)
		3/48 (6%)	0/45 (0%)	1/49 (2%)		8/48 (17%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	10/272 (3.68%)	Mean 3.7%	SD 2.74%	Total	23/291 (7.9%)	Mean 8.04%	SD 6.48%
Thyroid Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/45 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%
'Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%)	4/50 (8%)	7/50 (14%)		4/50 (8%)	3/50 (6%)	3/50 (6%)
		3/50 (6%)	11/45 (24%)	5/50 (10%)		7/49 (14%)	7/45 (16%)	7/50 (14%)
Overall Incidence	Total	35/295 (11.86%)	Mean 12.07%	SD 6.62%	Total	31/294 (10.54%)	Mean 10.64%	SD 4.44%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2014 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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 33 Report Date: 11/11/2014

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
	Tatal	0/50 (0%)	0/45 (0%)	0/50 (0%)	Tetal	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.33%	SD 0.82%	Total	2/294 (0.68%)	Mean 0.67%	SD 1.03%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/50 (12%)	4/50 (8%)	7/50 (14%)		5/50 (10%)	4/50 (8%)	3/50 (6%)
		3/50 (6%)	11/45 (24%)	5/50 (10%)		7/49 (14%)	7/45 (16%)	7/50 (14%)
Overall Incidence	Total	36/295 (12.2%)	Mean 12.41%	SD 6.54%	Total	33/294 (11.22%)	Mean 11.31%	SD 3.87%
*Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/45 (2%)	3/50 (6%)		0/49 (0%)	1/45 (2%)	3/50 (6%)
Overall Incidence	Total	5/295 (1.69%)	Mean 1.7%	SD 2.35%	Total	7/294 (2.38%)	Mean 2.37%	SD 1.96%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
	Tatal	0/50 (0%)	0/45 (0%)	0/50 (0%)	Tatal	1/49 (2%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	3/294 (1.02%)	Mean 1.01%	SD 1.1%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	1/45 (2%)	3/50 (6%)		1/49 (2%)	1/45 (2%)	3/50 (6%)
Overall Incidence	Total	5/295 (1.69%)	Mean 1.7%	SD 2.35%	Total	10/294 (3.4%)	Mean 3.38%	SD 1.59%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2014 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: ALL ROUTES Vehicle: ALL VEHICLES								Page: 34 Report Date: 11/11/2014					
					Male						F	emale		
*Urinary Bladder: Carcinoma or Papilloma		````	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50 1/50	(0%) (2%)		0/50 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)	0/50 1/50	(0%) (2%)
Overall Incidence	Total	1/299 (0.33%))	Mean 0.3	33%	SD 0.82%		Total	1/299 (0.	33%)	Mean	0.33%	SD 0.	82%
*Urinary Bladder: Papilloma		0/50 ((0%) (0%)	0/50 0/49	(0%) (0%)	0/50 1/50	(0%) (2%)		0/50 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)	0/50 1/50	(0%) (2%)
Overall Incidence	Total	1/299 (0.33%)	,	Mean 0.3	· · /	SD 0.82%	· · ·	Total	1/299 (0.	()		0.33%	SD 0.	· · ·
#Uterus: Adenoma									0/50 1/50	(0%) (2%)	0/50 1/50	(0%) (2%)	0/50 0/50	(0%) (0%)
Overall Incidence								Total	2/300 (0.	. ,		(2 <i>%</i>) 0.67%	SD 1.	· · ·
#Uterus: Carcinoma														
									3/50 1/50	(6%) (2%)	3/50 1/50	(6%) (2%)	1/50 3/50	(2%) (6%)
Overall Incidence								Total	12/300 ((4%)	Mea	n 4%	SD 2.	19%
#Uterus:														

Granular Cell Tumor Benign

(2%) 1/50 (2%) 0/50 (0%) 1/50 **Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% *: Denominator is number of animals with tissues examined microscopically

0/50

(0%)

0/50

(0%)

0/50

(0%)

Version: Nov2014 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: ALL ROUTES Vehicle: ALL VEHICLES	Page: 35 Report Date: 11/11/2014					
	Male		Female				
#Uterus: Hemangiosarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%			
#Uterus: Leiomyosarcoma		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
#Uterus: Malignant Mixed Mullerian Tumor		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
#Uterus: Polyp Stromal		2/50 (4%) 6/50 (12%)	3/50 (6%) 3/50 (6%)	5/50 (10%) 2/50 (4%)			
Overall Incidence	Total	21/300 (7%)	Mean 7%	2/50 (4%) SD 3.29%			
#Uterus: Sarcoma Stromal		1/50 (2%)	1/50 (2%)	2/50 (4%)			
Overall Incidence	Total	1/50 (2%) 5/300 (1.67%)	0/50 (0%) Mean 1.67%	0/50 (0%) SD 1.51%			

Tumor Incidence for Selected Control Animal Grou Route: ALL ROUTES Vehicle: ALL VEHICLES	Page: 36 Report Date: 11/11/2014					
Male		Female				
	3/50 (6%) 7/50 (14%)	4/50 (8%) 3/50 (6%)	6/50 (12%) 2/50 (4%)			
Total	25/300 (8.33%)	Mean 8.33%	SD 3.88%			
	0/50 (0%)	1/50 (2%)	0/50 (0%)			
Total		1/50 (2%)	0/50 (0%)			
l otal	4/300 (1.33%)	Mean 1.33%	SD 1.63%			
	0/50 (0%)	0/50 (0%)	1/50 (2%)			
Total	()	()	0/50 (0%) SD 0.82%			
	0/50 (0%)	0/50 (0%)	0/50 (0%)			
	· · /	()	0/50 (0%)			
l otal	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)			
Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
	Vehicle: ALL VEHICLES Male Total Total Total Total Total Total Total	Male 3/50 (6%) 7/50 (14%) Total 0/50 (0%) 2/50 (4%) Total 0/50 (0%) 2/50 (4%) 1/300 (1.33%) 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 1/50 (2%) Total 0/50 (0%) 1/300 (0.33%)	Male Female 3/50 (6%) 4/50 (8%) 7/50 (14%) 3/50 (6%) Total 25/300 (8.33%) Mean 8.33% Mean 8.33% 0/50 (0%) 1/50 (2%) 2/50 (4%) 1/50 (2%) Total 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%) Mean 0.33% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			

Version: Nov2014
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: ALL ROUTES Vehicle: ALL VEHICLES

Page: 37 Report Date: 11/11/2014

			Male			Female				
#Vagina:										
Polyp										
						0/50 (0%)	1/50 (2%)	0/50 (0%)		
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%		
#Zymbal's Gland: Carcinoma										
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%		
#Zymbal's Gland: Carcinoma or Adenoma										
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%		

*: Denominator is number of animals with tissues examined microscopically