



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

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.

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	M3	F1	F2	F3	
M4	M5		F4	F5		

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle 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
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		Male				Female			
#All Organs:									
Benign Tumors									
		34/50 (68%)	26/50 (52%)	32/50 (64%)		33/50 (66%)	38/50 (76%)	42/50 (84%)	
		24/50 (48%)	33/49 (67%)	30/50 (60%)		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 Tumors									
		36/50 (72%)	36/50 (72%)	37/50 (74%)		40/50 (80%)	43/50 (86%)	43/50 (86%)	
		26/50 (52%)	36/49 (73%)	34/50 (68%)		47/50 (94%)	40/50 (80%)	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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/49 (2%)	1/50 (2%)		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%)	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)	8/49 (16%)	3/50 (6%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	17/299 (5.69%)	Mean 5.72%	SD 5.97%	Total	8/300 (2.67%)	Mean 2.67%	SD 1.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		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: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		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%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)	
		1/50 (2%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	0/300 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		0/50 (0%)	2/50 (4%)	1/50 (2%)		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%	
.....									
#All Organs:									
Osteoma									
		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%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	1/50 (2%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
#All Organs:									
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%	
.....									
*Adrenal Cortex:									
Adenoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 2.34%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
*Adrenal Cortex:									
 Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Benign									
		1/49 (2%)	1/50 (2%)	4/50 (8%)		0/49 (0%)	1/50 (2%)	1/49 (2%)	
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	6/297 (2.02%)	Mean 2.01%	SD 3.1%	Total	5/297 (1.68%)	Mean 1.69%	SD 1.53%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Complex									
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	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 Malignant									
		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: Benign, Complex, Malignant, NOS									
		2/49 (4%)	1/50 (2%)	4/50 (8%)		0/49 (0%)	1/50 (2%)	2/49 (4%)	
		0/50 (0%)	1/49 (2%)	0/49 (0%)		0/50 (0%)	2/50 (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

#: Denominator is number of animals necropsied

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

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		Male				Female			
#Blood Vessel:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
*Bone Marrow:									
Hemangiosarcoma									
		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%	
.....									
#Bone:									
Osteoma									
		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%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	1/50 (2%)	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	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

#: Denominator is number of animals necropsied

Version: Nov2014
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
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		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%)	0/49 (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:									
Glioma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		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	2/299 (0.67%)	Mean 0.67%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)	1/50 (2%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Granular Cell Tumor Benign									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	3/300 (1%)	Mean 1%	SD 1.67%	
.....									
*Brain:									
Granular Cell Tumor Malignant									
		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

#: Denominator is number of animals necropsied

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 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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		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%)	0/49 (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:									
Meningioma: Benign, Malignant, 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, Glioma, or Astrocytoma									
		0/50 (0%)	1/50 (2%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		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%	
.....									
*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

#: Denominator is number of animals necropsied

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

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		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%	
.....									
#Intestine 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

#: Denominator is number of animals necropsied

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

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		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 Unspecified:									
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: Site Unspecified:									
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 Unspecified:									
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

#: Denominator is number of animals necropsied

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

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		Male				Female			
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (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 Transitional Epithelium:									
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%)	
		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:									
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

#: Denominator is number of animals necropsied

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

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 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%)	
		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	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 or 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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
*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%)	
		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%	
.....									
*Lung:									
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%	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%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangioma									
		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%	
.....									
#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

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

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 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%)	
		0/50 (0%)	7/49 (14%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	13/299 (4.35%)	Mean 4.38%	SD 5.38%	Total	5/300 (1.67%)	Mean 1.67%	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%)	
		0/50 (0%)	0/49 (0%)	0/50 (0%)		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

#: Denominator is number of animals necropsied

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

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 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, or 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

#: Denominator is number of animals necropsied

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

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 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%)	
		0/50 (0%)	0/49 (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	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
*Nose:									
Olfactory Neuroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (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	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		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 Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		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 Mucosa:									
Squamous Cell Carcinoma									
		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

#: Denominator is number of animals necropsied

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

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	Male	Female
*Ovary:		
Adenoma		
	2/50 (4%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 2/300 (0.67%)	Mean 0.67% SD 1.63%
.....		
*Ovary:		
Cystadenoma		
	1/50 (2%)	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		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	1/50 (2%)
Overall Incidence	Total 2/300 (0.67%)	Mean 0.67% SD 1.03%
.....		
*Ovary:		
Granulosa Cell Tumor Malignant		
	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%)	0/50 (0%)
	1/50 (2%)	2/50 (4%)
Overall Incidence	Total 5/300 (1.67%)	Mean 1.67% SD 1.51%

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

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

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 Report Date: 11/11/2014

					Male						Female							
*Ovary:																		
Sex Cord Stromal Tumor, Benign																		
					0/50	(0%)	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																		
					2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)						
					0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)						
Overall Incidence					Total	2/300 (0.67%)		Mean	0.67%		SD	1.63%						
.....																		
*Pancreas:																		
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%	
.....																		
*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%)					
		0/39	(0%)	2/47	(4%)	0/45	(0%)	1/42	(2%)	1/49	(2%)	0/48	(0%)					
Overall Incidence	Total	2/265 (0.75%)		Mean	0.71%		SD	1.74%		Total	2/272 (0.74%)		Mean	0.74%		SD	1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		14/50 (28%)	17/50 (34%)	16/49 (33%)		19/50 (38%)	32/50 (64%)	35/50 (70%)	
		14/50 (28%)	19/49 (39%)	21/50 (42%)		34/50 (68%)	23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	101/298 (33.89%)	Mean 33.9%	SD 5.67%	Total	164/300 (54.67%)	Mean 54.67%	SD 14.24%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (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	0/298 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		14/50 (28%)	17/50 (34%)	16/49 (33%)		20/50 (40%)	32/50 (64%)	35/50 (70%)	
		14/50 (28%)	19/49 (39%)	21/50 (42%)		34/50 (68%)	23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	101/298 (33.89%)	Mean 33.9%	SD 5.67%	Total	165/300 (55%)	Mean 55%	SD 13.78%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		1/50 (2%)	1/50 (2%)	2/49 (4%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
		1/50 (2%)	0/49 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	7/298 (2.35%)	Mean 2.35%	SD 1.52%	Total	9/300 (3%)	Mean 3%	SD 2.76%	
.....									
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		1/50 (2%)	1/50 (2%)	2/49 (4%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
		1/50 (2%)	0/49 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	7/298 (2.35%)	Mean 2.35%	SD 1.52%	Total	9/300 (3%)	Mean 3%	SD 2.76%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
*Prostate:									
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%					
.....									
*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%)	
		0/50 (0%)	1/46 (2%)	0/50 (0%)		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

#: Denominator is number of animals necropsied

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

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 Report Date: 11/11/2014

		Male				Female			
*Salivary Glands:									
Myoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/46 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/296 (0.68%)	Mean 0.67%	SD 1.03%	Total	0/299 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/46 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)	0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%					
.....									
#Skeletal Muscle:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/49 (2%)	0/50 (0%)	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%	
.....									
#Skeletal Muscle:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	1/50 (2%)	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

#: Denominator is number of animals necropsied

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

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		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 Basosquamous 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%	
.....									
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		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 Carcinoma									
		0/50 (0%)	0/50 (0%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or 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%)	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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		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 Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		1/50 (2%)	6/50 (12%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	3/49 (6%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	20/299 (6.69%)	Mean 6.69%	SD 5.16%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
#Skin:									
Fibroma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.27%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		2/50 (4%)	1/50 (2%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	7/299 (2.34%)	Mean 2.34%	SD 1.5%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	
.....									
#Skin:									
Fibrosarcoma									
		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%	

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

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

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		Male				Female			
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		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%	
.....									
#Skin:									
Hamartoma									
		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%	
.....									
#Skin:									
Hemangiosarcoma									
		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 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	2/49 (4%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	11/299 (3.68%)	Mean 3.68%	SD 2.34%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		0/50 (0%)	1/50 (2%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
#Skin:									
Liposarcoma									
		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%)	0/50 (0%)	
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant 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%	
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant 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%	
.....									
#Skin:									
Schwannoma Malignant									
		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%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		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

#: Denominator is number of animals necropsied

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

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 Report Date: 11/11/2014

		Male				Female			
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		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 Papilloma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		1/50 (2%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	2/49 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	14/299 (4.68%)	Mean 4.68%	SD 3.5%	Total	0/300 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	2/49 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	13/299 (4.35%)	Mean 4.35%	SD 3.2%	Total	0/300 (0%)	Mean 0%	SD 0%	

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

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

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		Male				Female			
#Skin: Sebaceous Gland:									
Adenoma									
		0/50 (0%)	1/50 (2%)	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	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 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%)	
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (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%)	
		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%)	
		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%	
.....									
#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

#: Denominator is number of animals necropsied

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

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		Male				Female			
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50 (0%)	1/50 (2%)	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%)	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%)	
		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%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		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%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma 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%)	
		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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		Male				Female			
#Stomach, Glandular:									
Fibrosarcoma									
		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%	
.....									
#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%)					
		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%)					
		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

#: Denominator is number of animals necropsied

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

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 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, Malignant, NOS									
		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

#: Denominator is number of animals necropsied

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

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		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%)	
		0/50 (0%)	0/45 (0%)	0/50 (0%)		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%)	
		0/50 (0%)	0/45 (0%)	0/50 (0%)		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

#: Denominator is number of animals necropsied

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

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		Male				Female			
*Urinary Bladder:									
Carcinoma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
*Urinary Bladder:									
Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	
.....									
#Uterus:									
Carcinoma									
						3/50 (6%)	3/50 (6%)	1/50 (2%)	
						1/50 (2%)	1/50 (2%)	3/50 (6%)	
Overall Incidence					Total	12/300 (4%)	Mean 4%	SD 2.19%	
.....									
#Uterus:									
Granular Cell Tumor Benign									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	

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

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

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	Male	Female
#Uterus:		
Hemangiosarcoma		
	1/50 (2%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
.....		
#Uterus:		
Leiomyosarcoma		
	1/50 (2%)	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%)
Overall Incidence	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
.....		
#Uterus:		
Polyp Stromal		
	2/50 (4%)	3/50 (6%)
	6/50 (12%)	3/50 (6%)
Overall Incidence	Total 21/300 (7%)	Mean 7% SD 3.29%
.....		
#Uterus:		
Sarcoma Stromal		
	1/50 (2%)	1/50 (2%)
	1/50 (2%)	0/50 (0%)
Overall Incidence	Total 5/300 (1.67%)	Mean 1.67% SD 1.51%

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

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

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	Male	Female
#Uterus:		
Sarcoma Stromal or Polyp Stromal		
	3/50 (6%)	4/50 (8%)
	7/50 (14%)	3/50 (6%)
Overall Incidence	Total 25/300 (8.33%)	Mean 8.33% SD 3.88%
.....		
#Uterus:		
Schwannoma Malignant		
	0/50 (0%)	1/50 (2%)
	2/50 (4%)	1/50 (2%)
Overall Incidence	Total 4/300 (1.33%)	Mean 1.33% SD 1.63%
.....		
#Uterus:		
Squamous Cell Papilloma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	1/50 (2%)
Overall Incidence	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
.....		
#Vagina:		
Fibrosarcoma		
	0/50 (0%)	0/50 (0%)
	1/50 (2%)	0/50 (0%)
Overall Incidence	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
.....		
#Vagina:		
Leiomyoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	1/50 (2%)
Overall Incidence	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

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		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
 #: Denominator is number of animals necropsied