



National Toxicology Program  
Department of Health and Human Services

# NTP Historical Controls Report

All Routes and Vehicles

Wistar-Han RATS

August 2016

# 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:

	<b>Male</b>			<b>Female</b>		
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: Aug2016  
 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: 08/04/2016

**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
<b>Male</b>							
Battelle Northwest	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Northwest	052072503	08/17/09	729	50(5)	36(692)	615.2	2,3-Butanedione
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 Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A
<b>Female</b>							
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Northwest	052072503	08/17/09	731	50(5)	34(688)	400.0	2,3-Butanedione
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 Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

Version: Aug2016  
 Contract/Lab: All Laboratories  
 Species: RATS  
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 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: 08/04/2016

		Male				Female			
<b>#All Organs:</b>									
<b>Benign Tumors</b>									
		34/50 (68%)	27/50 (54%)	26/50 (52%)		33/50 (66%)	39/50 (78%)	38/50 (76%)	
		32/50 (64%)	24/50 (48%)	33/49 (67%)		42/50 (84%)	42/50 (84%)	37/50 (74%)	
		30/50 (60%)				38/50 (76%)			
<b>Overall Incidence</b>	Total	206/349 (59.03%)	Mean 59.05%	SD 7.87%	Total	269/350 (76.86%)	Mean 76.86%	SD 6.2%	
.....									
<b>#All Organs:</b>									
<b>Malignant Tumors</b>									
		6/50 (12%)	13/50 (26%)	12/50 (24%)		17/50 (34%)	12/50 (24%)	16/50 (32%)	
		13/50 (26%)	4/50 (8%)	13/49 (27%)		11/50 (22%)	13/50 (26%)	10/50 (20%)	
		8/50 (16%)				10/50 (20%)			
<b>Overall Incidence</b>	Total	69/349 (19.77%)	Mean 19.79%	SD 7.68%	Total	89/350 (25.43%)	Mean 25.43%	SD 5.62%	
.....									
<b>#All Organs:</b>									
<b>Malignant and Benign Tumors</b>									
		36/50 (72%)	35/50 (70%)	36/50 (72%)		40/50 (80%)	40/50 (80%)	43/50 (86%)	
		37/50 (74%)	26/50 (52%)	36/49 (73%)		43/50 (86%)	47/50 (94%)	40/50 (80%)	
		34/50 (68%)				40/50 (80%)			
<b>Overall Incidence</b>	Total	240/349 (68.77%)	Mean 68.78%	SD 7.68%	Total	293/350 (83.71%)	Mean 83.71%	SD 5.35%	
.....									
<b>#All Organs:</b>									
<b>Hemangioma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	5/349 (1.43%)	Mean 1.43%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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: 5  
 Report Date: 08/04/2016

		Male				Female			
<b>#All Organs:</b>									
<b>Hemangiosarcoma</b>									
		3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	2/50 (4%)	
		3/50 (6%)	0/50 (0%)	8/49 (16%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		3/50 (6%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	20/349 (5.73%)	Mean 5.76%	SD 5.45%	Total	10/350 (2.86%)	Mean 2.86%	SD 1.57%	
.....									
<b>#All Organs:</b>									
<b>Hemangiosarcoma or Hemangioma</b>									
		4/50 (8%)	4/50 (8%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	2/50 (4%)	
		3/50 (6%)	1/50 (2%)	9/49 (18%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		4/50 (8%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	25/349 (7.16%)	Mean 7.2%	SD 5.87%	Total	11/350 (3.14%)	Mean 3.14%	SD 1.95%	
.....									
<b>#All Organs:</b>									
<b>Histiocytic Sarcoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%	
.....									
<b>#All Organs:</b>									
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>									
		1/50 (2%)	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%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)	Mean 0.86%	SD 1.08%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 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			
<b>#All Organs:</b>									
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>									
		0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		0/50 (0%)	1/50 (2%)	0/49 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	4/349 (1.15%)	Mean 1.14%	SD 2.27%	Total	5/350 (1.43%)	Mean 1.43%	SD 1.51%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Benign, Malignant, NOS</b>									
		0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	6/349 (1.72%)	Mean 1.71%	SD 1.8%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Malignant</b>									
		0/50 (0%)	1/50 (2%)	2/50 (4%)	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%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Osteoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#All Organs:</b>									
<b>Osteosarcoma</b>									
		0/50 (0%)	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%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.57%	SD 0.98%	Total	1/350 (0.29%)		Mean 0.29% SD 0.76%
.....									
<b>#All Organs:</b>									
<b>Osteosarcoma or Osteoma</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)		Mean 0.86%	SD 1.57%	Total	1/350 (0.29%)		Mean 0.29% SD 0.76%
.....									
<b>*Adrenal Cortex:</b>									
<b>Adenoma</b>									
		3/50 (6%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	0/49 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	9/349 (2.58%)		Mean 2.57%	SD 2.23%	Total	5/350 (1.43%)		Mean 1.43% SD 1.51%
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.58%	SD 0.99%	Total	1/350 (0.29%)		Mean 0.29% SD 0.76%

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

Version: Aug2016  
 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			
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Benign</b>									
		1/49 (2%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	3/50 (6%)	1/50 (2%)	
		4/50 (8%)	0/50 (0%)	0/49 (0%)		1/49 (2%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)				2/49 (4%)			
<b>Overall Incidence</b>	Total	7/347 (2.02%)	Mean 2.01%	SD 2.83%	Total	8/347 (2.31%)	Mean 2.3%	SD 2.15%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Complex</b>									
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)				0/49 (0%)			
<b>Overall Incidence</b>	Total	1/347 (0.29%)	Mean 0.29%	SD 0.77%	Total	1/347 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Malignant</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/49 (2%)		1/49 (2%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)				0/49 (0%)			
<b>Overall Incidence</b>	Total	1/347 (0.29%)	Mean 0.29%	SD 0.77%	Total	1/347 (0.29%)	Mean 0.29%	SD 0.77%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
		2/49 (4%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	3/50 (6%)	1/50 (2%)	
		4/50 (8%)	0/50 (0%)	1/49 (2%)		2/49 (4%)	0/50 (0%)	2/50 (4%)	
		0/49 (0%)				2/49 (4%)			
<b>Overall Incidence</b>	Total	9/347 (2.59%)	Mean 2.59%	SD 2.77%	Total	10/347 (2.88%)	Mean 2.88%	SD 2.28%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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								
<b>#Blood Vessel:</b>														
<b>Hemangiosarcoma</b>														
		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%)			
		1/50	(2%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	0/350 (0%)		Mean	0%	SD	0%
.....														
<b>*Bone Marrow:</b>														
<b>Hemangiosarcoma</b>														
		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%)					
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	0/350 (0%)		Mean	0%	SD	0%
.....														
<b>#Bone:</b>														
<b>Osteoma</b>														
		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%)					
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	0/350 (0%)		Mean	0%	SD	0%
.....														
<b>#Bone:</b>														
<b>Osteosarcoma</b>														
		0/50	(0%)	0/50	(0%)	1/50	(2%)	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%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 Contract/Lab: All Laboratories  
 Species: RATS  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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		Male				Female			
<b>#Bone:</b>									
<b>Osteosarcoma or Osteoma</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)		Mean 0.86%	SD 1.57%	Total 1/350 (0.29%)		Mean 0.29%	SD 0.76%
.....									
<b>#Bone:</b>									
<b>Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.76%	Total 0/350 (0%)		Mean 0%	SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.57%	SD 1.51%	Total 0/350 (0%)		Mean 0%	SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma Malignant</b>									
		0/50 (0%)	1/50 (2%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)		Mean 0.86%	SD 1.08%	Total 0/350 (0%)		Mean 0%	SD 0%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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: 08/04/2016

		Male				Female			
<b>*Brain:</b>									
<b>Granular Cell Tumor Benign</b>									
		1/50 (2%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/49 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	8/349 (2.29%)	Mean 2.29%	SD 2.14%	Total	4/350 (1.14%)	Mean 1.14%	SD 1.57%	
.....									
<b>*Brain:</b>									
<b>Granular Cell Tumor Malignant</b>									
		0/50 (0%)	1/50 (2%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Brain:</b>									
<b>Meningioma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Meningioma: Benign, Malignant, NOS</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 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			
<b>*Brain:</b>									
<b>Oligodendroglioma Benign</b>									
		0/50 (0%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
<b>*Brain:</b>									
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	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%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)	Mean 0.86%	SD 1.08%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
<b>*Clitoral/Preputial Gland:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/348 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/347 (0%)	Mean 0%	SD 0%	
<b>*Clitoral/Preputial Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/348 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/347 (0%)	Mean 0%	SD 0%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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						
<b>*Heart:</b>												
<b>Schwannoma Benign</b>												
		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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%		Total	1/350 (0.29%)		Mean 0.29%	SD 0.76%
.....												
<b>*Heart:</b>												
<b>Schwannoma NOS</b>												
		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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%		Total	0/350 (0%)		Mean 0%	SD 0%
.....												
<b>#Intestine Small: Duodenum:</b>												
<b>Fibroma</b>												
		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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.77%		Total	0/350 (0%)		Mean 0%	SD 0%
.....												
<b>#Intestine Small: Duodenum:</b>												
<b>Leiomyosarcoma</b>												
		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%)			
<b>Overall Incidence</b>	Total	0/349 (0%)		Mean 0%		SD 0%		Total	1/350 (0.29%)		Mean 0.29%	SD 0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyoma</b>									
		0/50 (0%)	1/50 (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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.76%	Total 1/350 (0.29%)		Mean 0.29%	SD 0.76%
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyosarcoma</b>									
		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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	0/349 (0%)		Mean 0%	SD 0%	Total 1/350 (0.29%)		Mean 0.29%	SD 0.76%
.....									
<b>#Intestine Small: Site Unspecified:</b>									
<b>Fibroma</b>									
		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%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.77%	Total 0/350 (0%)		Mean 0%	SD 0%
.....									
<b>#Intestine Small: Site Unspecified:</b>									
<b>Leiomyoma</b>									
		0/50 (0%)	1/50 (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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.76%	Total 1/350 (0.29%)		Mean 0.29%	SD 0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Intestine Small: Site Unspecified:</b>									
<b>Leiomyosarcoma</b>									
		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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	5/50 (10%)	4/49 (8%)		1/49 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	10/349 (2.87%)	Mean 2.88%	SD 4.33%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Carcinoma</b>									
		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%)	2/49 (4%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)	Mean 0.58%	SD 1.54%	Total	0/349 (0%)	Mean 0%	SD 0%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	5/50 (10%)	6/49 (12%)		1/49 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	12/349 (3.44%)	Mean 3.46%	SD 5.32%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	

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

Version: Aug2016  
 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			
<b>*Kidney: Pelvis and Transitional Epithelium:</b>									
<b>Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Adenoma</b>									
		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%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>*Kidney: Renal Tubule:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Liposarcoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>Cholangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	3/350 (0.86%)	Mean 0.86%	SD 2.27%	
.....									
<b>*Liver:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>*Liver:</b>									
<b>Hepatocellular Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	4/349 (1.15%)	Mean 1.16%	SD 2.31%	Total	6/350 (1.71%)	Mean 1.71%	SD 2.14%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	4/349 (1.15%)	Mean 1.16%	SD 2.31%	Total	6/350 (1.71%)	Mean 1.71%	SD 2.14%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	4/349 (1.15%)	Mean 1.16%	SD 2.31%	Total	6/350 (1.71%)	Mean 1.71%	SD 2.14%	
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Adenoma</b>									
		3/50 (6%)	1/50 (2%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 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: 08/04/2016

		Male				Female			
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>									
		3/50 (6%)	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%)	0/49 (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%)			
<b>Overall Incidence</b>	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Lymph Node:</b>									
<b>Hemangioma</b>									
		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%)	1/50 (2%)	0/49 (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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Lymph Node, Mandibular:</b>									
<b>Hemangioma</b>									
		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%)	0/50 (0%)	0/49 (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%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Lymph Node, Mesenteric:</b>									
<b>Hemangioma</b>									
		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%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)	Mean 0.86%	SD 1.08%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 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			
<b>#Lymph Node, Mesenteric: Hemangiosarcoma</b>									
		2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)		
		3/50 (6%)	0/50 (0%)	7/49 (14%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		1/50 (2%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	15/349 (4.3%)	Mean 4.33%	SD 4.92%	Total	7/350 (2%)	Mean 2%	SD 1.63%	
.....									
<b>#Mammary Gland: Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	5/50 (10%)	2/50 (4%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%)	4/50 (8%)	0/50 (0%)	
		0/50 (0%)				4/50 (8%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	17/350 (4.86%)	Mean 4.86%	SD 3.98%	
.....									
<b>#Mammary Gland: Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	5/50 (10%)	4/50 (8%)	6/50 (12%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)	4/50 (8%)	4/50 (8%)	1/50 (2%)		
		0/50 (0%)			1/50 (2%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	25/350 (7.14%)	Mean 7.14%	SD 3.8%	
.....									
<b>#Mammary Gland: Carcinoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	5/50 (10%)	8/50 (16%)	8/50 (16%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)	6/50 (12%)	8/50 (16%)	1/50 (2%)		
		0/50 (0%)			4/50 (8%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	40/350 (11.43%)	Mean 11.43%	SD 5.26%	

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

Version: Aug2016  
 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			
<b>#Mammary Gland:</b>									
<b>Fibroadenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	13/50 (26%)	11/50 (22%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		9/50 (18%)	2/50 (4%)	9/50 (18%)	
		1/50 (2%)				8/50 (16%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	59/350 (16.86%)	Mean 16.86%	SD 6.91%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		7/50 (14%)	15/50 (30%)	11/50 (22%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		11/50 (22%)	6/50 (12%)	9/50 (18%)	
		1/50 (2%)				12/50 (24%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	71/350 (20.29%)	Mean 20.29%	SD 6.16%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		10/50 (20%)	15/50 (30%)	15/50 (30%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		13/50 (26%)	9/50 (18%)	10/50 (20%)	
		1/50 (2%)				12/50 (24%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	84/350 (24%)	Mean 24%	SD 4.9%	
.....									
<b>#Mesentery:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Mesentery:</b>									
<b>Lipoma</b>									
		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%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.77%	Total	0/350 (0%)
								Mean	0%
								SD	0%
<b>#Mesentery:</b>									
<b>Schwannoma Malignant</b>									
		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%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	0/350 (0%)
								Mean	0%
								SD	0%
<b>*Nose:</b>									
<b>Adenoma</b>									
		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%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	0/349 (0%)
								Mean	0%
								SD	0%
<b>*Nose:</b>									
<b>Chondroma</b>									
		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%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%	Total	1/349 (0.29%)
								Mean	0.29%
								SD	0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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								
<b>*Nose:</b>														
<b>  Olfactory Neuroblastoma</b>														
		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%)					
<b>Overall Incidence</b>	Total	0/349 (0%)		Mean	0%	SD	0%	Total	1/349 (0.29%)		Mean	0.29%	SD	0.76%
.....														
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>														
<b>  Squamous Cell Carcinoma</b>														
		0/50	(0%)	1/50	(2%)	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%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%
.....														
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>														
<b>  Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>														
		0/50	(0%)	1/50	(2%)	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%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%
.....														
<b>#Oral Mucosa:</b>														
<b>  Squamous Cell Carcinoma</b>														
		0/50	(0%)	1/50	(2%)	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%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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
<b>*Ovary:</b>		
<b>Adenoma</b>		
	2/50 (4%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total 2/350 (0.57%)	Mean 0.57% SD 1.51%
.....		
<b>*Ovary:</b>		
<b>Cystadenoma</b>		
	1/50 (2%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
.....		
<b>*Ovary:</b>		
<b>Granulosa Cell Tumor Benign</b>		
	0/50 (0%)	0/50 (0%)
	1/50 (2%)	0/50 (0%)
	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total 2/350 (0.57%)	Mean 0.57% SD 0.98%
.....		
<b>*Ovary:</b>		
<b>Granulosa Cell Tumor Malignant</b>		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	1/50 (2%)
	1/50 (2%)	1/50 (2%)
<b>Overall Incidence</b>	Total 3/350 (0.86%)	Mean 0.86% SD 1.07%

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

Version: Aug2016  
 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			
<b>*Ovary:</b>							
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	2/50	(4%)
		1/50	(2%)				
<b>Overall Incidence</b>	Total	5/350 (1.43%)		Mean	1.43%	SD	1.51%
.....							
<b>*Ovary:</b>							
<b>Granulosa-Theca Tumor Malignant</b>							
		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)				
<b>Overall Incidence</b>	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%
.....							
<b>*Ovary:</b>							
<b>Sex Cord Stromal Tumor, Benign</b>							
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)				
<b>Overall Incidence</b>	Total	2/350 (0.57%)		Mean	0.57%	SD	1.51%
.....							
<b>*Ovary:</b>							
<b>Tubulostromal Adenoma</b>							
		2/50	(4%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)				
<b>Overall Incidence</b>	Total	3/350 (0.86%)		Mean	0.86%	SD	1.57%

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

Version: Aug2016  
 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			
<b>*Pancreas:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/46 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	4/346 (1.16%)	Mean 1.17%	SD 1.09%	Total	0/349 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/46 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	4/346 (1.16%)	Mean 1.17%	SD 1.09%	Total	0/349 (0%)	Mean 0%	SD 0%	
.....									
<b>*Parathyroid Gland:</b>									
<b>Adenoma</b>									
		0/44 (0%)	1/49 (2%)	0/47 (0%)	0/39 (0%)	0/46 (0%)	0/47 (0%)	0/47 (0%)	0/47 (0%)
		0/43 (0%)	0/39 (0%)	2/47 (4%)	0/47 (0%)	1/42 (2%)	1/49 (2%)	1/49 (2%)	1/49 (2%)
		0/45 (0%)			0/48 (0%)				
<b>Overall Incidence</b>	Total	3/314 (0.96%)	Mean 0.9%	SD 1.66%	Total	2/318 (0.63%)	Mean 0.63%	SD 1.08%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Adenoma</b>									
		14/50 (28%)	9/50 (18%)	17/50 (34%)	19/50 (38%)	26/50 (52%)	32/50 (64%)	32/50 (64%)	32/50 (64%)
		16/49 (33%)	14/50 (28%)	19/49 (39%)	35/50 (70%)	34/50 (68%)	23/50 (46%)	23/50 (46%)	23/50 (46%)
		21/50 (42%)			21/50 (42%)				
<b>Overall Incidence</b>	Total	110/348 (31.61%)	Mean 31.63%	SD 7.93%	Total	190/350 (54.29%)	Mean 54.29%	SD 13.03%	

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

Version: Aug2016  
 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			
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>  Carcinoma</b>									
		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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>  Carcinoma or Adenoma</b>									
		14/50 (28%)	9/50 (18%)	17/50 (34%)	20/50 (40%)	26/50 (52%)	32/50 (64%)		
		16/49 (33%)	14/50 (28%)	19/49 (39%)	35/50 (70%)	34/50 (68%)	23/50 (46%)		
		21/50 (42%)			21/50 (42%)				
<b>Overall Incidence</b>	Total	110/348 (31.61%)	Mean 31.63%	SD 7.93%	Total	191/350 (54.57%)	Mean 54.57%	SD 12.63%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>  Adenoma</b>									
		1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)		
		2/49 (4%)	1/50 (2%)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)		
		2/50 (4%)			4/50 (8%)				
<b>Overall Incidence</b>	Total	9/348 (2.59%)	Mean 2.58%	SD 1.52%	Total	10/350 (2.86%)	Mean 2.86%	SD 2.54%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>  Carcinoma or Adenoma</b>									
		1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)		
		2/49 (4%)	1/50 (2%)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)		
		2/50 (4%)			4/50 (8%)				
<b>Overall Incidence</b>	Total	9/348 (2.59%)	Mean 2.58%	SD 1.52%	Total	10/350 (2.86%)	Mean 2.86%	SD 2.54%	

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

Version: Aug2016  
 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					
<b>*Prostate:</b>											
<b>Adenoma</b>											
		1/50	(2%)	0/50	(0%)	0/50	(0%)				
		1/50	(2%)	0/50	(0%)	0/49	(0%)				
		0/50	(0%)								
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.57%		SD 0.98%					
.....											
<b>*Prostate:</b>											
<b>Carcinoma</b>											
		0/50	(0%)	1/50	(2%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/49	(0%)				
		0/50	(0%)								
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%					
.....											
<b>*Prostate:</b>											
<b>Carcinoma or Adenoma</b>											
		1/50	(2%)	1/50	(2%)	0/50	(0%)				
		1/50	(2%)	0/50	(0%)	0/49	(0%)				
		0/50	(0%)								
<b>Overall Incidence</b>	Total	3/349 (0.86%)		Mean 0.86%		SD 1.07%					
.....											
<b>*Salivary Glands:</b>											
<b>Adenoma</b>											
		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%)		
<b>Overall Incidence</b>	Total	1/346 (0.29%)		Mean 0.31%		SD 0.82%		Total	0/349 (0%)	Mean 0%	SD 0%

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

Version: Aug2016  
 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							
<b>*Salivary Glands:</b>													
<b>  Carcinoma</b>													
		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%)		
		0/50	(0%)					0/50	(0%)	1/50	(2%)		
<b>Overall Incidence</b>	<b>Total</b>	0/346 (0%)		Mean 0%		SD 0%		Total 1/349 (0.29%)		Mean 0.29%		SD 0.76%	
.....													
<b>*Salivary Glands:</b>													
<b>  Carcinoma or Adenoma</b>													
		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%)	1/50	(2%)		
<b>Overall Incidence</b>	<b>Total</b>	1/346 (0.29%)		Mean 0.31%		SD 0.82%		Total 1/349 (0.29%)		Mean 0.29%		SD 0.76%	
.....													
<b>*Salivary Glands:</b>													
<b>  Myoepithelioma</b>													
		1/50	(2%)	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%)				
<b>Overall Incidence</b>	<b>Total</b>	2/346 (0.58%)		Mean 0.57%		SD 0.98%		Total 0/349 (0%)		Mean 0%		SD 0%	
.....													
<b>*Salivary Glands:</b>													
<b>  Schwannoma Malignant</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)		
		1/50	(2%)	0/50	(0%)	0/46	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)				
<b>Overall Incidence</b>	<b>Total</b>	1/346 (0.29%)		Mean 0.29%		SD 0.76%		Total 0/349 (0%)		Mean 0%		SD 0%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Seminal Vesicle:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	0/49	(0%)		
		0/50	(0%)						
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%			
.....									
<b>#Skeletal Muscle:</b>									
<b>Hemangiosarcoma</b>									
		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%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.77%		Total	0/350 (0%)
								Mean	0%
								SD	0%
.....									
<b>#Skeletal Muscle:</b>									
<b>Sarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)					0/50	(0%)
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%		Total	0/350 (0%)
								Mean	0%
								SD	0%
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma</b>									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)
		2/50	(4%)					0/50	(0%)
<b>Overall Incidence</b>	Total	5/349 (1.43%)		Mean 1.43%		SD 1.9%		Total	1/350 (0.29%)
								Mean	0.29%
								SD	0.76%

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

Version: Aug2016  
 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								
<b>#Skin:</b>														
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>														
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)			
		2/50	(4%)					0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	5/349 (1.43%)		Mean	1.43%	SD	1.9%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%
<b>#Skin:</b>														
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>														
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)			
		0/50	(0%)	0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)			
		2/50	(4%)					0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	5/349 (1.43%)		Mean	1.43%	SD	1.9%	Total	1/350 (0.29%)		Mean	0.29%	SD	0.76%
<b>#Skin:</b>														
<b>Basal Cell Carcinoma</b>														
		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%)			
		1/50	(2%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	0/350 (0%)		Mean	0%	SD	0%
<b>#Skin:</b>														
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>														
		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%)			
		1/50	(2%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean	0.57%	SD	0.98%	Total	0/350 (0%)		Mean	0%	SD	0%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Skin:</b>									
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		2/50 (4%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	6/349 (1.72%)	Mean 1.72%	SD 1.8%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Skin:</b>									
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>									
		1/50 (2%)	3/50 (6%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		7/50 (14%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	23/349 (6.59%)	Mean 6.59%	SD 4.72%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Skin:</b>									
<b>Fibroma</b>									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	6/349 (1.72%)	Mean 1.72%	SD 1.38%	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%	
.....									
<b>#Skin:</b>									
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	9/349 (2.58%)	Mean 2.58%	SD 1.51%	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%	

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

Version: Aug2016  
 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: 08/04/2016

		Male				Female			
<b>#Skin:</b>									
<b>Fibrosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>									
		0/50 (0%)	1/50 (2%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Hamartoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 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			
<b>#Skin:</b>									
<b>Hemangiosarcoma</b>									
		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%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			1/50 (2%)				
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Skin:</b>									
<b>Keratoacanthoma</b>									
		1/50 (2%)	3/50 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	14/349 (4.01%)	Mean 4.01%	SD 2.31%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	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%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Liposarcoma</b>									
		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%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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							
<b>#Skin:</b>													
<b>Myxoma</b>													
		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%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%		Total	0/350 (0%)		Mean 0%	SD 0%	
.....													
<b>#Skin:</b>													
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)					0/50	(0%)				
<b>Overall Incidence</b>	Total	4/349 (1.15%)		Mean 1.14%		SD 1.95%		Total	2/350 (0.57%)		Mean 0.57%	SD 1.51%	
.....													
<b>#Skin:</b>													
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)					0/50	(0%)				
<b>Overall Incidence</b>	Total	4/349 (1.15%)		Mean 1.14%		SD 1.95%		Total	2/350 (0.57%)		Mean 0.57%	SD 1.51%	
.....													
<b>#Skin:</b>													
<b>Schwannoma Malignant</b>													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)					0/50	(0%)				
<b>Overall Incidence</b>	Total	4/349 (1.15%)		Mean 1.14%		SD 1.95%		Total	2/350 (0.57%)		Mean 0.57%	SD 1.51%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.76%	Total	0/350 (0%)		Mean 0% SD 0%
.....									
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>									
		0/50 (0%)	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%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/349 (0.86%)		Mean 0.86%	SD 1.07%	Total	0/350 (0%)		Mean 0% SD 0%
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.57%	SD 0.98%	Total	0/350 (0%)		Mean 0% SD 0%
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma or Papilloma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/349 (0.57%)		Mean 0.57%	SD 0.98%	Total	0/350 (0%)		Mean 0% SD 0%

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

Version: Aug2016  
 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			
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>									
		1/50 (2%)	3/50 (6%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		5/50 (10%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	17/349 (4.87%)	Mean 4.87%	SD 3.23%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>									
		1/50 (2%)	3/50 (6%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		5/50 (10%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	16/349 (4.58%)	Mean 4.58%	SD 2.99%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin: Sebaceous Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	1/50 (2%)	1/50 (2%)	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%)	
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	3/349 (0.86%)	Mean 0.86%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin: Sebaceous Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	1/50 (2%)	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%)	
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	3/349 (0.86%)	Mean 0.86%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%	

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

Version: Aug2016  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar-Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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		Male				Female			
<b>*Spleen:</b>									
<b>Hemangiosarcoma</b>									
		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%)	0/50 (0%)	1/47 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	3/347 (0.86%)	Mean 0.88%	SD 1.09%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Fibrosarcoma</b>									
		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%)	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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Leiomyoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	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%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Leiomyosarcoma</b>									
		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%)	0/50 (0%)	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%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar-Han  
 Length of Study: CHRONIC

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 Route: ALL ROUTES  
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		Male				Female			
<b>#Stomach, Forestomach:</b>									
<b>Sarcoma</b>									
		0/50 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma</b>									
		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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	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%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Stomach, Glandular:</b>									
<b>Fibrosarcoma</b>									
		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%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Glandular:</b>									
<b>Leiomyosarcoma</b>									
		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%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/349 (0%)	Mean 0%	SD 0%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	
.....									
<b>#Stomach, Glandular:</b>									
<b>Sarcoma</b>									
		0/50 (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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%	
.....									
<b>*Testes:</b>									
<b>Adenoma</b>									
		6/50 (12%)	3/50 (6%)	2/50 (4%)					
		2/50 (4%)	0/50 (0%)	2/49 (4%)					
		0/50 (0%)							
<b>Overall Incidence</b>	Total	15/349 (4.3%)	Mean 4.3%	SD 4.07%					

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

Version: Aug2016  
 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			
<b>*Testes:</b>									
<b>Hemangiosarcoma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/49	(0%)		
		0/50	(0%)						
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%		SD 0.76%			
.....									
<b>*Thymus:</b>									
<b>Sarcoma</b>									
		0/41	(0%)	0/47	(0%)	0/49	(0%)	0/46	(0%)
		0/40	(0%)	0/48	(0%)	0/45	(0%)	0/48	(0%)
		0/49	(0%)					1/50	(2%)
<b>Overall Incidence</b>	Total	0/319 (0%)		Mean 0%		SD 0%		Total	1/340 (0.29%)
								Mean	0.29%
								SD	0.76%
.....									
<b>*Thymus:</b>									
<b>Thymoma Benign</b>									
		3/41	(7%)	1/47	(2%)	2/49	(4%)	6/46	(13%)
		1/40	(3%)	3/48	(6%)	0/45	(0%)	5/48	(10%)
		1/49	(2%)					8/48	(17%)
<b>Overall Incidence</b>	Total	11/319 (3.45%)		Mean 3.47%		SD 2.57%		Total	23/340 (6.76%)
								Mean	6.89%
								SD	6.65%
.....									
<b>*Thymus:</b>									
<b>Thymoma: Benign, Malignant, NOS</b>									
		3/41	(7%)	1/47	(2%)	2/49	(4%)	6/46	(13%)
		1/40	(3%)	3/48	(6%)	0/45	(0%)	5/48	(10%)
		1/49	(2%)					8/48	(17%)
<b>Overall Incidence</b>	Total	11/319 (3.45%)		Mean 3.47%		SD 2.57%		Total	23/340 (6.76%)
								Mean	6.89%
								SD	6.65%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>*Thyroid Gland: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/45 (0%)	0/50 (0%)	0/49 (0%)	0/45 (0%)		
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	0/345 (0%)	Mean 0%	SD 0%	Total	1/344 (0.29%)	Mean 0.29%	SD 0.76%	
.....									
<b>*Thyroid Gland: C-Cell: Adenoma</b>									
		5/50 (10%)	6/50 (12%)	4/50 (8%)	4/50 (8%)	2/50 (4%)	3/50 (6%)		
		7/50 (14%)	3/50 (6%)	11/45 (24%)	3/50 (6%)	7/49 (14%)	7/45 (16%)		
		5/50 (10%)			7/50 (14%)				
<b>Overall Incidence</b>	Total	41/345 (11.88%)	Mean 12.06%	SD 6.04%	Total	33/344 (9.59%)	Mean 9.69%	SD 4.77%	
.....									
<b>*Thyroid Gland: C-Cell: Carcinoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	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%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/345 (0.29%)	Mean 0.29%	SD 0.76%	Total	3/344 (0.87%)	Mean 0.86%	SD 1.07%	
.....									
<b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b>									
		6/50 (12%)	6/50 (12%)	4/50 (8%)	5/50 (10%)	3/50 (6%)	4/50 (8%)		
		7/50 (14%)	3/50 (6%)	11/45 (24%)	3/50 (6%)	7/49 (14%)	7/45 (16%)		
		5/50 (10%)			7/50 (14%)				
<b>Overall Incidence</b>	Total	42/345 (12.17%)	Mean 12.35%	SD 5.97%	Total	36/344 (10.47%)	Mean 10.55%	SD 4.06%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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  
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		Male				Female			
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)		
		1/50 (2%)	0/50 (0%)	1/45 (2%)	1/50 (2%)	0/49 (0%)	1/45 (2%)		
		3/50 (6%)			3/50 (6%)				
<b>Overall Incidence</b>	Total	7/345 (2.03%)	Mean 2.03%	SD 2.31%	Total	9/344 (2.62%)	Mean 2.6%	SD 1.89%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/45 (0%)	1/50 (2%)	1/49 (2%)	0/45 (0%)		
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	0/345 (0%)	Mean 0%	SD 0%	Total	3/344 (0.87%)	Mean 0.86%	SD 1.08%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)		
		1/50 (2%)	0/50 (0%)	1/45 (2%)	2/50 (4%)	1/49 (2%)	1/45 (2%)		
		3/50 (6%)			3/50 (6%)				
<b>Overall Incidence</b>	Total	7/345 (2.03%)	Mean 2.03%	SD 2.31%	Total	12/344 (3.49%)	Mean 3.47%	SD 1.47%	
.....									
<b>*Urinary Bladder: Carcinoma or Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)			1/50 (2%)				
<b>Overall Incidence</b>	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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  
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		Male				Female			
<b>*Urinary Bladder:</b>									
<b>Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/349 (0.29%)		Mean 0.29%	SD 0.76%	Total 1/349 (0.29%)		Mean 0.29%	SD 0.76%
.....									
<b>#Uterus:</b>									
<b>Adenoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	1/50 (2%)	1/50 (2%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total					2/350 (0.57%)		Mean 0.57%	SD 0.98%
.....									
<b>#Uterus:</b>									
<b>Carcinoma</b>									
						3/50 (6%)	2/50 (4%)	3/50 (6%)	
						1/50 (2%)	1/50 (2%)	1/50 (2%)	
						3/50 (6%)			
<b>Overall Incidence</b>	Total					14/350 (4%)		Mean 4%	SD 2%
.....									
<b>#Uterus:</b>									
<b>Granular Cell Tumor Benign</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	1/50 (2%)	1/50 (2%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total					2/350 (0.57%)		Mean 0.57%	SD 0.98%

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

Version: Aug2016  
 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		
<b>#Uterus:</b>						
<b>Hemangiosarcoma</b>						
		1/50	(2%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	1/350 (0.29%)		Mean	0.29%	SD 0.76%
.....						
<b>#Uterus:</b>						
<b>Leiomyosarcoma</b>						
		1/50	(2%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	1/350 (0.29%)		Mean	0.29%	SD 0.76%
.....						
<b>#Uterus:</b>						
<b>Malignant Mixed Mullerian Tumor</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	1/50 (2%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	1/350 (0.29%)		Mean	0.29%	SD 0.76%
.....						
<b>#Uterus:</b>						
<b>Polyp Stromal</b>						
		2/50	(4%)	9/50	(18%)	3/50 (6%)
		5/50	(10%)	6/50	(12%)	3/50 (6%)
		2/50	(4%)			
<b>Overall Incidence</b>	Total	30/350 (8.57%)		Mean	8.57%	SD 5.13%

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

Version: Aug2016  
 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		
<b>#Uterus:</b>						
<b>Sarcoma Stromal</b>						
		1/50	(2%)	1/50	(2%)	1/50 (2%)
		2/50	(4%)	1/50	(2%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	6/350 (1.71%)		Mean	1.71%	SD 1.38%
.....						
<b>#Uterus:</b>						
<b>Sarcoma Stromal or Polyp Stromal</b>						
		3/50	(6%)	10/50	(20%)	4/50 (8%)
		6/50	(12%)	7/50	(14%)	3/50 (6%)
		2/50	(4%)			
<b>Overall Incidence</b>	Total	35/350 (10%)		Mean	10%	SD 5.66%
.....						
<b>#Uterus:</b>						
<b>Schwannoma Malignant</b>						
		0/50	(0%)	1/50	(2%)	1/50 (2%)
		0/50	(0%)	2/50	(4%)	1/50 (2%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	5/350 (1.43%)		Mean	1.43%	SD 1.51%
.....						
<b>#Uterus:</b>						
<b>Squamous Cell Papilloma</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/50	(2%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	1/350 (0.29%)		Mean	0.29%	SD 0.76%

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016  
 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			
<b>#Vagina:</b>									
<b>Fibrosarcoma</b>									
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	1/50	(2%)	0/50	(0%)
				0/50	(0%)				
<b>Overall Incidence</b>				Total	1/350 (0.29%)	Mean	0.29%	SD	0.76%
.....									
<b>#Vagina:</b>									
<b>Leiomyoma</b>									
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				1/50	(2%)				
<b>Overall Incidence</b>				Total	1/350 (0.29%)	Mean	0.29%	SD	0.76%
.....									
<b>#Vagina:</b>									
<b>Polyp</b>									
				0/50	(0%)	0/50	(0%)	1/50	(2%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)				
<b>Overall Incidence</b>				Total	1/350 (0.29%)	Mean	0.29%	SD	0.76%
.....									
<b>#Zymbal's Gland:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		2/50	(4%)	1/50	(2%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	4/349 (1.15%)		Mean	1.14%	SD	1.57%	Total	0/350 (0%)
								Mean	0%
								SD	0%

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

Version: Aug2016  
 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  
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		Male				Female			
<b>#Zymbal's Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	4/349 (1.15%)	Mean 1.14%	SD 1.57%	Total	0/350 (0%)	Mean 0%	SD 0%	

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