

**Version:** Jun2013  
**Contract/Lab:** All Laboratories  
**Species:** RATS  
**Strain:** Wistar Han  
**Length of Study:** CHRONIC

**Toxicology Data Management System**  
Tumor Incidence for Selected Control Animal Groups  
**Route:** GAVAGE  
**Vehicle:** WATER

**Page:** 28  
**Report Date:** 06/12/2013

### Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
<b>Male</b>							
Battelle Columbus Laboratory	052020303	07/18/07	727	50(3)	35(687)	632.7	Green tea extract
<b>Female</b>							
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green tea extract

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 29  
 Report Date: 06/12/2013

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

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 30  
 Report Date: 06/12/2013

	Male				Female			
<b>#All Organs:</b>								
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#All Organs:</b>								
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>								
		0/50	(0%)			1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50	(2%)
								Mean 2%
								SD 0%
.....								
<b>#All Organs:</b>								
<b>Mesothelioma: Benign, Malignant, NOS</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#All Organs:</b>								
<b>Mesothelioma: Malignant</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#All Organs:</b>								
<b>Osteoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#All Organs:</b>								
<b>Osteosarcoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 31  
 Report Date: 06/12/2013

	Male				Female			
<b>#All Organs:</b>								
<b>Osteosarcoma or Osteoma</b>								
		2/50 (4%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>*Adrenal Cortex:</b>								
<b>Adenoma</b>								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>*Adrenal Cortex:</b>								
<b>Carcinoma</b>								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>*Adrenal Medulla:</b>								
<b>Pheochromocytoma Benign</b>								
		1/50 (2%)			1/50 (2%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
.....								
<b>*Adrenal Medulla:</b>								
<b>Pheochromocytoma Malignant</b>								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>*Adrenal Medulla:</b>								
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>								
		1/50 (2%)			1/50 (2%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 32  
 Report Date: 06/12/2013

	Male				Female			
<b>#Blood Vessel:</b>								
<b>Hemangiosarcoma</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>*Bone Marrow:</b>								
<b>Hemangiosarcoma</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Bone:</b>								
<b>Osteoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Bone:</b>								
<b>Osteosarcoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Bone:</b>								
<b>Osteosarcoma or Osteoma</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Bone:</b>								
<b>Sarcoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 33  
 Report Date: 06/12/2013

		Male				Female			
<b>*Brain:</b>									
<b>Glioma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma Malignant</b>									
		1/50	(2%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Brain:</b>									
<b>Granular Cell Tumor Benign</b>									
		2/50	(4%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Brain:</b>									
<b>Meningioma Malignant</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Brain:</b>									
<b>Meningioma: Benign, Malignant, NOS</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>									
		1/50	(2%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 34  
 Report Date: 06/12/2013

		Male			Female		
<b>*Clitoral/Preputial Gland: Carcinoma</b>							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0% SD 0%
.....							
<b>*Clitoral/Preputial Gland: Carcinoma or Adenoma</b>							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0% SD 0%
.....							
<b>*Heart: Schwannoma Benign</b>							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0% SD 0%
.....							
<b>#Intestine Small: Duodenum: Leiomyosarcoma</b>							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0% SD 0%
.....							
<b>#Intestine Small: Jejunum: Leiomyosarcoma</b>							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2% SD 0%
.....							
<b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b>							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2% SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 35  
 Report Date: 06/12/2013

		Male				Female			
<b>*Islets, Pancreatic:</b>									
<b>Adenoma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Islets, Pancreatic:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Pelvis and Transitional Epithelium:</b>									
<b>Papilloma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Adenoma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Lipoma</b>									
		0/50	(0%)			1/50	(2%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50	(2%)	Mean 2% SD 0%

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



Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 36  
 Report Date: 06/12/2013

		Male			Female		
<b>*Kidney: Renal Tubule:</b>							
<b>Liposarcoma</b>							
		1/50	(2%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50 (0%)
							Mean 0%
							SD 0%
<b>*Liver:</b>							
<b>Hepatocellular Adenoma</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
							Mean 2%
							SD 0%
<b>*Liver:</b>							
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
							Mean 2%
							SD 0%
<b>*Liver:</b>							
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
							Mean 2%
							SD 0%
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Adenoma</b>							
		0/50	(0%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
							Mean 0%
							SD 0%
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>							
		0/50	(0%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
							Mean 0%
							SD 0%

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 37  
 Report Date: 06/12/2013

		Male				Female			
<b>#Lymph Node, Mesenteric: Hemangioma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)	Mean 0% SD 0%
.....									
<b>#Lymph Node, Mesenteric: Hemangiosarcoma</b>									
		0/50	(0%)			1/50	(2%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50	(2%)	Mean 2% SD 0%
.....									
<b>#Mammary Gland: Adenoma</b>									
		0/50	(0%)			2/50	(4%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/50	(4%)	Mean 4% SD 0%
.....									
<b>#Mammary Gland: Carcinoma</b>									
		0/50	(0%)			6/50	(12%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	6/50	(12%)	Mean 12% SD 0%
.....									
<b>#Mammary Gland: Carcinoma or Adenoma</b>									
		0/50	(0%)			8/50	(16%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	8/50	(16%)	Mean 16% SD 0%
.....									
<b>#Mammary Gland: Fibroadenoma</b>									
		0/50	(0%)			11/50	(22%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	11/50	(22%)	Mean 22% SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 38  
 Report Date: 06/12/2013

	Male				Female				
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma or Adenoma</b>									
		0/50	(0%)			11/50	(22%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>									
		0/50	(0%)			15/50	(30%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	15/50 (30%)	Mean 30%	SD 0%
.....									
<b>#Mesentery:</b>									
<b>Hemangiosarcoma</b>									
		0/50	(0%)			1/50	(2%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
.....									
<b>#Mesentery:</b>									
<b>Schwannoma Malignant</b>									
		1/50	(2%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....									
<b>*Nose:</b>									
<b>Olfactory Neuroblastoma</b>									
		0/50	(0%)			0/49	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma</b>									
		1/50	(2%)			1/50	(2%)		
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
.....									

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 39  
 Report Date: 06/12/2013

	Male				Female			
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>								
		1/50 (2%)			1/50 (2%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
.....								
<b>#Oral Mucosa: Squamous Cell Carcinoma</b>								
		1/50 (2%)			1/50 (2%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
.....								
<b>*Ovary: Granulosa Cell Tumor Benign</b>								
					0/50 (0%)			
<b>Overall Incidence</b>	Total				0/50 (0%)	Mean 0%	SD 0%	
.....								
<b>*Ovary: Granulosa Cell Tumor Malignant</b>								
					0/50 (0%)			
<b>Overall Incidence</b>	Total				0/50 (0%)	Mean 0%	SD 0%	
.....								
<b>*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS</b>								
					0/50 (0%)			
<b>Overall Incidence</b>	Total				0/50 (0%)	Mean 0%	SD 0%	
.....								
<b>*Ovary: Sex Cord Stromal Tumor, Benign</b>								
					0/50 (0%)			
<b>Overall Incidence</b>	Total				0/50 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 40  
 Report Date: 06/12/2013

		Male			Female		
<b>*Pancreas:</b>							
<b>Adenoma</b>							
		0/50 (0%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0% SD 0%
.....							
<b>*Pancreas:</b>							
<b>Carcinoma or Adenoma</b>							
		0/50 (0%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0% SD 0%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Adenoma</b>							
		17/50 (34%)			32/50 (64%)		
<b>Overall Incidence</b>	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64% SD 0%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Carcinoma or Adenoma</b>							
		17/50 (34%)			32/50 (64%)		
<b>Overall Incidence</b>	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64% SD 0%
.....							
<b>*Pituitary Gland: Pars Intermedia:</b>							
<b>Adenoma</b>							
		1/50 (2%)			2/50 (4%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4% SD 0%
.....							
<b>*Pituitary Gland: Pars Intermedia:</b>							
<b>Carcinoma or Adenoma</b>							
		1/50 (2%)			2/50 (4%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4% SD 0%

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 41  
 Report Date: 06/12/2013

		Male				Female			
<b>*Prostate:</b>									
<b>Adenoma</b>									
		0/50	(0%)						
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%				
.....									
<b>*Prostate:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)						
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%				
.....									
<b>*Salivary Glands:</b>									
<b>Myoepithelioma</b>									
		0/50	(0%)			0/49	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	0/49	(0%)	Mean 0%	SD 0%
.....									
<b>*Salivary Glands:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)			0/49	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	0/49	(0%)	Mean 0%	SD 0%
.....									
<b>#Seminal Vesicle:</b>									
<b>Adenoma</b>									
		0/50	(0%)						
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%				
.....									
<b>#Skeletal Muscle:</b>									
<b>Sarcoma</b>									
		0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	0/50	(0%)	Mean 0%	SD 0%
.....									

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 42  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Basal Cell Adenoma</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
							Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
							Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
							Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Basal Cell Carcinoma</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(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%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
							Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
							Mean 0%	SD 0%

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 43  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma								
		6/50 (12%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
Fibroma								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
Fibrosarcoma								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
<b>#Skin:</b>								
Hamartoma								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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



Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 44  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Hemangiosarcoma</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
.....								
<b>#Skin:</b>								
<b>Keratoacanthoma</b>								
		2/50	(4%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	0/50	(0%)
.....								
<b>#Skin:</b>								
<b>Lipoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
.....								
<b>#Skin:</b>								
<b>Liposarcoma</b>								
		0/50	(0%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50	(0%)
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>								
		2/50	(4%)			2/50	(4%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	2/50	(4%)
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>								
		2/50	(4%)			2/50	(4%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	2/50	(4%)
.....								

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 45  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Schwannoma Malignant</b>								
		2/50	(4%)			2/50	(4%)	
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%	Total	2/50	(4%)
								Mean 4%
								SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Carcinoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma or Papilloma</b>								
		1/50	(2%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>								
		4/50	(8%)			0/50	(0%)	
<b>Overall Incidence</b>	Total	4/50	(8%)	Mean 8%	SD 0%	Total	0/50	(0%)
								Mean 0%
								SD 0%
.....								

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 46  
 Report Date: 06/12/2013

	Male				Female			
<b>#Skin:</b>								
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>								
		3/50 (6%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin: Sebaceous Gland:</b>								
<b>Adenoma</b>								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin: Sebaceous Gland:</b>								
<b>Carcinoma or Adenoma</b>								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>*Spleen:</b>								
<b>Hemangiosarcoma</b>								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Leiomyoma</b>								
		0/50 (0%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>#Stomach, Forestomach:</b>								
<b>Leiomyosarcoma</b>								
		1/50 (2%)			0/50 (0%)			
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 47  
 Report Date: 06/12/2013

		Male			Female		
<b>#Stomach, Forestomach:</b>							
<b>Sarcoma</b>							
		0/50	(0%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
<b>#Stomach, Forestomach:</b>							
<b>Squamous Cell Carcinoma</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
.....							
<b>#Stomach, Forestomach:</b>							
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
.....							
<b>#Stomach, Glandular:</b>							
<b>Leiomyosarcoma</b>							
		0/50	(0%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
<b>#Stomach, Glandular:</b>							
<b>Sarcoma</b>							
		0/50	(0%)		0/50	(0%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)
.....							
<b>*Testes:</b>							
<b>Adenoma</b>							
		2/50	(4%)				
<b>Overall Incidence</b>	Total	2/50	(4%)	Mean 4%	SD 0%		
.....							

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

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 48  
 Report Date: 06/12/2013

		Male			Female		
<b>*Thymus:</b>							
<b>Sarcoma</b>							
		0/49	(0%)		0/49	(0%)	
<b>Overall Incidence</b>	Total	0/49	(0%)	Mean 0%	SD 0%	Total	0/49 (0%)
.....							
<b>*Thymus:</b>							
<b>Thymoma Benign</b>							
		2/49	(4%)		3/49	(6%)	
<b>Overall Incidence</b>	Total	2/49	(4.08%)	Mean 4.08%	SD 0%	Total	3/49 (6.12%)
.....							
<b>*Thymus:</b>							
<b>Thymoma: Benign, Malignant, NOS</b>							
		2/49	(4%)		3/49	(6%)	
<b>Overall Incidence</b>	Total	2/49	(4.08%)	Mean 4.08%	SD 0%	Total	3/49 (6.12%)
.....							
<b>*Thyroid Gland: C-Cell:</b>							
<b>Adenoma</b>							
		4/50	(8%)		3/50	(6%)	
<b>Overall Incidence</b>	Total	4/50	(8%)	Mean 8%	SD 0%	Total	3/50 (6%)
.....							
<b>*Thyroid Gland: C-Cell:</b>							
<b>Carcinoma</b>							
		0/50	(0%)		1/50	(2%)	
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)
.....							
<b>*Thyroid Gland: C-Cell:</b>							
<b>Carcinoma or Adenoma</b>							
		4/50	(8%)		4/50	(8%)	
<b>Overall Incidence</b>	Total	4/50	(8%)	Mean 8%	SD 0%	Total	4/50 (8%)
.....							

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 49  
 Report Date: 06/12/2013

		Male				Female			
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
.....									
<b>*Urinary Bladder: Carcinoma or Papilloma</b>									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
.....									
<b>*Urinary Bladder: Papilloma</b>									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
.....									
<b>#Uterus: Carcinoma</b>									
Overall Incidence					Total	3/50 (6%)	Mean 6%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 50  
 Report Date: 06/12/2013

	Male	Female
<b>#Uterus:</b>		
<b>Polyp Stromal</b>		
Overall Incidence	Total 3/50 (6%)	Mean 6% SD 0%
<b>#Uterus:</b>		
<b>Sarcoma Stromal</b>		
Overall Incidence	Total 1/50 (2%)	Mean 2% SD 0%
<b>#Uterus:</b>		
<b>Sarcoma Stromal or Polyp Stromal</b>		
Overall Incidence	Total 4/50 (8%)	Mean 8% SD 0%
<b>#Uterus:</b>		
<b>Schwannoma Malignant</b>		
Overall Incidence	Total 1/50 (2%)	Mean 2% SD 0%
<b>#Uterus:</b>		
<b>Squamous Cell Papilloma</b>		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%
<b>#Vagina:</b>		
<b>Leiomyoma</b>		
Overall Incidence	Total 0/50 (0%)	Mean 0% SD 0%

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

#: Denominator is number of animals necropsied

Version: Jun2013  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Wistar Han  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
 Vehicle: WATER

Page: 51  
 Report Date: 06/12/2013

Male					Female			
<b>#Vagina:</b>								
<b>Polyp</b>								
					1/50	(2%)		
<b>Overall Incidence</b>					Total	1/50 (2%)	Mean 2%	SD 0%
.....								
<b>#Zymbal's Gland:</b>								
<b>Carcinoma</b>								
					1/50	(2%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								
<b>#Zymbal's Gland:</b>								
<b>Carcinoma or Adenoma</b>								
					1/50	(2%)		
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
.....								

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

#: Denominator is number of animals necropsied