

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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

Page: 96
Report Date: 05/18/2011

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng
Battelle Columbus Laboratory	059501107	03/06/02	727	50(3)	22(673)	510.3	5-(Hydroxymethyl)-2-furfural
Female							
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng
Battelle Columbus Laboratory	059501107	03/07/02	728	50(5)	31(679)	332.2	5-(Hydroxymethyl)-2-furfural

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 97
 Report Date: 05/18/2011

		Male			Female		
#All Organs:							
Benign Tumors							
		49/50 (98%)	50/50 (100%)		42/50 (84%)	46/50 (92%)	
Overall Incidence	Total	99/100 (99%)	Mean 99%	SD 1.41%	Total	88/100 (88%)	Mean 88% SD 5.66%
.....							
#All Organs:							
Malignant Tumors							
		26/50 (52%)	35/50 (70%)		10/50 (20%)	16/50 (32%)	
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 12.73%	Total	26/100 (26%)	Mean 26% SD 8.49%
.....							
#All Organs:							
Malignant and Benign Tumors							
		49/50 (98%)	50/50 (100%)		45/50 (90%)	48/50 (96%)	
Overall Incidence	Total	99/100 (99%)	Mean 99%	SD 1.41%	Total	93/100 (93%)	Mean 93% SD 4.24%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 98
 Report Date: 05/18/2011

		Male			Female		
#All Organs:							
Histiocytic Sarcoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Leukemia: Erythrocytic							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated							
		18/50 (36%)	28/50 (56%)		6/50 (12%)	9/50 (18%)	
Overall Incidence	Total	46/100 (46%)	Mean 46%	SD 14.14%	Total	15/100 (15%)	Mean 15% SD 4.24%
.....							
#All Organs:							
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Mesothelioma: Benign							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Mesothelioma: Benign, Malignant, NOS							
		2/50 (4%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 99
 Report Date: 05/18/2011

		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		2/50	(4%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	4/100	(4%)	Mean 4%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Osteoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#All Organs:									
Osteosarcoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
#All Organs:									
Osteosarcoma or Osteoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
*Adrenal Cortex:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 100
 Report Date: 05/18/2011

		Male				Female			
*Adrenal Medulla: Ganglioneuroma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Adrenal Medulla: Hemangioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Adrenal Medulla: Pheochromocytoma Benign									
		4/50	(8%)	5/50	(10%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	9/100	(9%)	Mean 9%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
*Adrenal Medulla: Pheochromocytoma Complex									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Adrenal Medulla: Pheochromocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS									
		4/50	(8%)	5/50	(10%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	9/100	(9%)	Mean 9%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 101
 Report Date: 05/18/2011

		Male				Female			
#Bone:									
Chordoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Bone:									
Osteoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Bone:									
Osteosarcoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Bone:									
Osteosarcoma or Osteoma									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
*Brain:									
Astrocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Ependymoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 102
 Report Date: 05/18/2011

		Male				Female			
*Brain:									
Ependymoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Glioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Glioma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Glioma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Granular Cell Tumor Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Brain:									
Oligodendroglioma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 103
 Report Date: 05/18/2011

		Male				Female					
*Brain:											
Oligodendroglioma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Oligodendroglioma, Glioma, or Astrocytoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Osteosarcoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Clitoral/Preputial Gland:											
Adenoma											
		0/50	(0%)	5/50	(10%)			1/50	(2%)	3/50	(6%)
Overall Incidence	Total	5/100	(5%)	Mean 5%	SD 7.07%	Total	4/100	(4%)	Mean 4%	SD 2.83%	
.....											
*Clitoral/Preputial Gland:											
Carcinoma											
		0/50	(0%)	1/50	(2%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 104
 Report Date: 05/18/2011

		Male				Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		0/50 (0%)	6/50 (12%)			2/50 (4%)	3/50 (6%)		
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 8.49%	Total	5/100 (5%)	Mean 5%	SD 1.41%	
.....									
*Clitoral/Preputial Gland: Sarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Ear: Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Esophagus: Lipoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Eye: Melanoma Benign									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Eye: Melanoma Malignant									
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 105
 Report Date: 05/18/2011

		Male				Female					
#Eye:											
Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Harderian Gland:											
Adenoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Harderian Gland:											
Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Harderian Gland:											
Carcinoma or Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Heart:											
Schwannoma Benign											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Heart:											
Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 106
 Report Date: 05/18/2011

		Male				Female			
#Intestine Large: Colon/Rectum: Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Intestine Large: Colon/Rectum: Hemangioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Intestine Small: Duodenum: Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Intestine Small: Duodenum: Leiomyoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Intestine Small: Duodenum: Schwannoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 107
 Report Date: 05/18/2011

		Male				Female					
#Intestine Small: Ileum:											
Adenoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Jejunum:											
Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Jejunum:											
Granular Cell Tumor Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Jejunum:											
Leiomyoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Jejunum:											
Leiomyosarcoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified:											
Adenoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 108
 Report Date: 05/18/2011

		Male				Female					
#Intestine Small: Site Unspecified: Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Carcinoma or Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Leiomyoma											
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Intestine Small: Site Unspecified: Leiomyosarcoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 109
 Report Date: 05/18/2011

		Male				Female					
*Islets, Pancreatic: Adenoma											
		0/50	(0%)	2/50	(4%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Islets, Pancreatic: Carcinoma											
		0/50	(0%)	2/50	(4%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Islets, Pancreatic: Carcinoma or Adenoma											
		0/50	(0%)	4/50	(8%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	4/100	(4%)	Mean 4%	SD 5.66%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
*Kidney: Pelvis and Transitional Epithelium: Carcinoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Pelvis and Transitional Epithelium: Papilloma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 110
 Report Date: 05/18/2011

		Male				Female					
*Kidney: Renal Tubule: Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule: Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule: Carcinoma or Adenoma											
		2/50	(4%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule: Hemangiosarcoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule: Lipoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule: Mesenchymal Tumor Benign											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 111
 Report Date: 05/18/2011

		Male				Female			
*Kidney: Renal Tubule:									
Mesenchymal Tumor Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Kidney: Renal Tubule:									
Nephroblastoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Kidney: Renal Tubule:									
Sarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Liver:									
Cholangioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Liver:									
Hemangiosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Liver:									
Hepatocellular Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 112
 Report Date: 05/18/2011

		Male				Female					
*Liver:											
Hepatocellular Carcinoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Hepatocellular Carcinoma or Hepatoblastoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Hepatocellular Carcinoma or Hepatocellular Adenoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Ito Cell Tumor Benign											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Lung:											
Alveolar/Bronchiolar Adenoma											
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 113
 Report Date: 05/18/2011

		Male				Female				
*Lung:										
Alveolar/Bronchiolar Carcinoma										
		0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Lung:										
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma										
		0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%
.....										
*Lung:										
Fibrosarcoma										
		0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Lung:										
Hemangiosarcoma										
		0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Lung:										
Squamous Cell Carcinoma										
		0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%
.....										
#Lymph Node:										
Hemangiosarcoma										
		0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 114
 Report Date: 05/18/2011

		Male				Female			
#Mammary Gland:									
Adenolipoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#Mammary Gland:									
Adenoma									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	2/50	(4%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	4/100	(4%)	Mean 4%
									SD 0%
.....									
#Mammary Gland:									
Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#Mammary Gland:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	2/50	(4%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	4/100	(4%)	Mean 4%
									SD 0%
.....									
#Mammary Gland:									
Fibroadenoma									
		2/50	(4%)	1/50	(2%)	32/50	(64%)	29/50	(58%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	61/100	(61%)	Mean 61%
									SD 4.24%
.....									
#Mammary Gland:									
Fibroma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 115
 Report Date: 05/18/2011

		Male				Female			
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		2/50 (4%)	1/50 (2%)			33/50 (66%)	30/50 (60%)		
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	63/100 (63%)	Mean 63%	SD 4.24%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		2/50 (4%)	1/50 (2%)			33/50 (66%)	30/50 (60%)		
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	63/100 (63%)	Mean 63%	SD 4.24%	
.....									
#Mesentery:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Lipoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 116
 Report Date: 05/18/2011

		Male				Female			
*Nose:									
Adenoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
*Nose:									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Papilloma Squamous or Papilloma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 117
 Report Date: 05/18/2011

	Male				Female			
#Oral Mucosa:								
Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Cystadenoma								
					0/50 (0%)	0/49 (0%)		
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Fibrosarcoma								
					0/50 (0%)	0/49 (0%)		
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Granulosa Cell Tumor Benign								
					0/50 (0%)	0/49 (0%)		
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Granulosa Cell Tumor Malignant								
					0/50 (0%)	0/49 (0%)		
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Granulosa Cell Tumor: Benign, Malignant, NOS								
					0/50 (0%)	0/49 (0%)		
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 118
 Report Date: 05/18/2011

		Male			Female		
*Ovary:							
Granulosa-Theca Tumor Benign							
			0/50 (0%)		0/49 (0%)		
Overall Incidence		Total	0/99 (0%)		Mean 0%		SD 0%
.....							
*Ovary:							
Granulosa-Theca Tumor Malignant							
			0/50 (0%)		0/49 (0%)		
Overall Incidence		Total	0/99 (0%)		Mean 0%		SD 0%
.....							
*Ovary:							
Schwannoma Malignant							
			0/50 (0%)		0/49 (0%)		
Overall Incidence		Total	0/99 (0%)		Mean 0%		SD 0%
.....							
*Ovary:							
Tubulostromal Adenoma							
			0/50 (0%)		0/49 (0%)		
Overall Incidence		Total	0/99 (0%)		Mean 0%		SD 0%
.....							
*Pancreas:							
Adenoma							
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%
							SD 0%
.....							
*Pancreas:							
Carcinoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%
							SD 0%
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 119
 Report Date: 05/18/2011

		Male				Female					
*Pancreas:											
Carcinoma or Adenoma											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Pancreas:											
Mixed Tumor Benign											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Pancreas:											
Mixed Tumor Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Parathyroid Gland:											
Adenoma											
		0/50	(0%)	0/49	(0%)			0/48	(0%)	0/48	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/96	(0%)	Mean 0%	SD 0%	
.....											
*Pituitary Gland: Pars Distalis or Unspecified Site:											
Adenoma											
		20/50	(40%)	15/50	(30%)			16/50	(32%)	24/50	(48%)
Overall Incidence	Total	35/100	(35%)	Mean 35%	SD 7.07%	Total	40/100	(40%)	Mean 40%	SD 11.31%	
.....											
*Pituitary Gland: Pars Distalis or Unspecified Site:											
Carcinoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%	SD 1.41%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 120
 Report Date: 05/18/2011

		Male			Female		
*Pituitary Gland: Pars Distalis or Unspecified Site:							
 Carcinoma or Adenoma							
		20/50 (40%)	15/50 (30%)		16/50 (32%)	25/50 (50%)	
Overall Incidence	Total	35/100 (35%)	Mean 35%	SD 7.07%	Total	41/100 (41%)	Mean 41% SD 12.73%
.....							
*Pituitary Gland: Pars Distalis or Unspecified Site:							
 Ganglioneuroma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
*Pituitary Gland: Pars Intermedia:							
 Adenoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
*Pituitary Gland: Pars Intermedia:							
 Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
*Pituitary Gland: Pars Nervosa:							
 Craniopharyngioma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
*Prostate:							
 Adenoma							
		1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 121
 Report Date: 05/18/2011

		Male				Female			
*Prostate:									
 Carcinoma or Adenoma									
		1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%				
.....									
*Salivary Glands:									
 Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
*Salivary Glands:									
 Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
*Salivary Glands:									
 Sarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
*Salivary Glands:									
 Schwannoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
#Seminal Vesicle:									
 Adenoma									
		1/50	(2%)	0/50	(0%)				
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%				

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 122
 Report Date: 05/18/2011

		Male				Female			
#Skeletal Muscle:									
Fibrous Histiocytoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skeletal Muscle:									
Hemangiosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma or Rhabdomyoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Skin:									
Basal Cell Adenoma									
		1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 123
 Report Date: 05/18/2011

	Male					Female					
#Skin:											
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
		1/50	(2%)	1/50	(2%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	2/100 (2%)		Mean 2%	SD 0%	Total	1/100 (1%)		Mean 1%	SD 1.41%	
.....											
#Skin:											
Basal Cell Carcinoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%	Total	0/100 (0%)		Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100 (0%)		Mean 0%	SD 0%	Total	0/100 (0%)		Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
		1/50	(2%)	1/50	(2%)			1/50	(2%)	0/50	(0%)
Overall Incidence	Total	2/100 (2%)		Mean 2%	SD 0%	Total	1/100 (1%)		Mean 1%	SD 1.41%	
.....											
#Skin:											
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma											
		2/50	(4%)	4/50	(8%)			3/50	(6%)	0/50	(0%)
Overall Incidence	Total	6/100 (6%)		Mean 6%	SD 2.83%	Total	3/100 (3%)		Mean 3%	SD 4.24%	
.....											
#Skin:											
Fibroma											
		2/50	(4%)	5/50	(10%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	7/100 (7%)		Mean 7%	SD 4.24%	Total	1/100 (1%)		Mean 1%	SD 1.41%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 124
 Report Date: 05/18/2011

	Male				Female			
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
		3/50 (6%)	6/50 (12%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Fibrosarcoma								
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Fibrous Histiocytoma								
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangioma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 125
 Report Date: 05/18/2011

		Male				Female					
#Skin:											
Keratoacanthoma											
		0/50	(0%)	2/50	(4%)			2/50	(4%)	0/50	(0%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	2/100	(2%)	Mean 2%	SD 2.83%	
.....											
#Skin:											
Lipoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Liposarcoma											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Neural Crest Tumor											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Neural Crest Tumor, Malignant											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Neurofibroma or Schwannoma benign											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 126
 Report Date: 05/18/2011

	Male				Female			
#Skin:								
Neurofibrosarcoma or Schwannoma (malignant or NOS)								
		0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)								
		0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Sarcoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Schwannoma Benign								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Skin:								
Squamous Cell Carcinoma								
		1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 127
 Report Date: 05/18/2011

	Male				Female			
#Skin:								
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:								
Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin:								
Squamous Cell Papilloma or Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin:								
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
Overall Incidence	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%
#Skin:								
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%
#Skin:								
Trichoepithelioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 128
 Report Date: 05/18/2011

		Male				Female			
#Skin: Sebaceous Gland:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Spinal Cord:									
Astrocytoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Spinal Cord:									
Astrocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Spinal Cord:									
Glioma Malignant									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
*Spleen:									
Fibrosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 129
 Report Date: 05/18/2011

		Male				Female			
*Spleen:									
Fibrous Histiocytoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Spleen:									
Hemangiosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Spleen:									
Leiomyosarcoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
*Spleen:									
Sarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1% SD 1.41%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 130
 Report Date: 05/18/2011

	Male				Female			
#Stomach, Forestomach:								
Squamous Cell Carcinoma or Papilloma Squamous								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
#Stomach, Forestomach:								
Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Carcinoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Lipoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Sarcoma								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 131
 Report Date: 05/18/2011

		Male				Female			
*Testes:									
Adenoma									
		45/50 (90%)	48/50 (96%)						
Overall Incidence	Total	93/100 (93%)	Mean 93%	SD 4.24%					
.....									
*Testes:									
Hemangioma									
		0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%					
.....									
*Thymus:									
Thymoma Benign									
		0/50 (0%)	0/48 (0%)		0/48 (0%)	1/48 (2%)			
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total 1/96 (1.04%)	Mean 1.04%	SD 1.47%		
.....									
*Thymus:									
Thymoma Malignant									
		0/50 (0%)	0/48 (0%)		1/48 (2%)	0/48 (0%)			
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total 1/96 (1.04%)	Mean 1.04%	SD 1.47%		
.....									
*Thymus:									
Thymoma NOS									
		0/50 (0%)	0/48 (0%)		0/48 (0%)	0/48 (0%)			
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total 0/96 (0%)	Mean 0%	SD 0%		
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/50 (0%)	0/48 (0%)		1/48 (2%)	1/48 (2%)			
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total 2/96 (2.08%)	Mean 2.08%	SD 0%		

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 132
 Report Date: 05/18/2011

		Male				Female				
*Thyroid Gland: C-Cell: Adenoma										
Overall Incidence	Total	11/50 (22%)	1/50 (2%)	Mean 12%	SD 14.14%	Total	6/50 (12%)	11/50 (22%)	Mean 17%	SD 7.07%
.....										
*Thyroid Gland: C-Cell: Carcinoma										
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	1/50 (2%)	Mean 1%	SD 1.41%
.....										
*Thyroid Gland: C-Cell: Carcinoma or Adenoma										
Overall Incidence	Total	11/50 (22%)	1/50 (2%)	Mean 12%	SD 14.14%	Total	6/50 (12%)	12/50 (24%)	Mean 18%	SD 8.49%
.....										
*Thyroid Gland: Follicular Cell: Adenoma										
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	Mean 1%	SD 1.41%	Total	0/50 (0%)	1/50 (2%)	Mean 1%	SD 1.41%
.....										
*Thyroid Gland: Follicular Cell: Carcinoma										
Overall Incidence	Total	1/50 (2%)	2/50 (4%)	Mean 3%	SD 1.41%	Total	0/50 (0%)	2/50 (4%)	Mean 2%	SD 2.83%
.....										
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
Overall Incidence	Total	1/50 (2%)	3/50 (6%)	Mean 4%	SD 2.83%	Total	0/50 (0%)	2/50 (4%)	Mean 2%	SD 2.83%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 133
 Report Date: 05/18/2011

		Male				Female			
#Tissue NOS:									
Paranglioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Tongue:									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Tongue:									
Squamous Cell Papilloma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Tooth:									
Adamantinoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Tooth:									
Odontoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 134
 Report Date: 05/18/2011

		Male				Female			
*Urinary Bladder: Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Urinary Bladder: Carcinoma or Papilloma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Urinary Bladder: Hemangiosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Urinary Bladder: Papilloma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Uterus: Adenoma									
						0/50	(0%)	0/50	(0%)
Overall Incidence						0/100	(0%)	Mean 0%	SD 0%
.....									
#Uterus: Carcinoma									
						0/50	(0%)	0/50	(0%)
Overall Incidence						0/100	(0%)	Mean 0%	SD 0%
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 135
 Report Date: 05/18/2011

	Male	Female
#Uterus: Deciduoma Benign		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Leiomyosarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Polyp Stromal		
Overall Incidence	Total 8/50 (16%) 16/100 (16%)	8/50 (16%) Mean 16% SD 0%
#Uterus: Sarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Sarcoma Stromal		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		
Overall Incidence	Total 8/50 (16%) 16/100 (16%)	8/50 (16%) Mean 16% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

Page: 136
 Report Date: 05/18/2011

		Male			Female		
#Uterus:							
Schwannoma Malignant							
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%		
.....							
#Vagina:							
Polyp							
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%		
.....							
#Vagina:							
Sarcoma							
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%		
.....							
#Vagina:							
Schwannoma Malignant							
			0/50 (0%)		0/50 (0%)		
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%		
.....							
#Zymbal's Gland:							
Adenoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%
.....							
#Zymbal's Gland:							
Carcinoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%
.....							

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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

Page: 137
Report Date: 05/18/2011

	Male				Female			
#Zymbal's Gland:								
Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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