

Version: May2009  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

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

Page: 98  
Report Date:04/29/2009

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	058812305	03/21/01	727	50 (3)	26(673)	509.7	Formamide
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
<b>Female</b>							
Battelle Columbus Laboratory	058812305	03/20/01	730	50 (5)	38(703)	358.3	Formamide
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

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 99  
 Report Date:04/29/2009

		Male			Female		
<b>#All Organs: Benign Tumors</b>							
		45/50 (90%)	49/50 (98%)	50/50 (100%)	43/50 (86%)	42/50 (84%)	46/50 (92%)
<b>Overall Incidence</b>	Total	144/150 (96%)	Mean 96%	SD 5.29%	Total 131/150 (87.33%)	Mean 87.33%	SD 4.16%
.....							
<b>#All Organs: Malignant Tumors</b>							
		25/50 (50%)	26/50 (52%)	35/50 (70%)	15/50 (30%)	10/50 (20%)	16/50 (32%)
<b>Overall Incidence</b>	Total	86/150 (57.33%)	Mean 57.33%	SD 11.02%	Total 41/150 (27.33%)	Mean 27.33%	SD 6.43%
.....							
<b>#All Organs: Malignant and Benign Tumors</b>							
		48/50 (96%)	49/50 (98%)	50/50 (100%)	49/50 (98%)	45/50 (90%)	48/50 (96%)
<b>Overall Incidence</b>	Total	147/150 (98%)	Mean 98%	SD 2%	Total 142/150 (94.67%)	Mean 94.67%	SD 4.16%
.....							
<b>#All Organs: Hemangioma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>#All Organs: Hemangiosarcoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>#All Organs: Hemangiosarcoma or Hemangioma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

**Page: 100**  
**Report Date:04/29/2009**

		Male				Female								
<b>#All Organs:</b>														
<b>Histiocytic Sarcoma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#All Organs:</b>														
<b>Leukemia: Erythrocytic</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#All Organs:</b>														
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>														
		15/50	(30%)	18/50	(36%)	28/50	(56%)	10/50	(20%)	6/50	(12%)	9/50	(18%)	
<b>Overall Incidence</b>	Total	61/150	(40.67%)	Mean	40.67%	SD	13.61%	Total	25/150	(16.67%)	Mean	16.67%	SD	4.16%
.....														
<b>#All Organs:</b>														
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#All Organs:</b>														
<b>Mesothelioma: Benign</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#All Organs:</b>														
<b>Mesothelioma: Benign, Malignant, NOS</b>														
		2/50	(4%)	2/50	(4%)	2/50	(4%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	6/150	(4%)	Mean	4%	SD	0%	Total	2/150	(1.33%)	Mean	1.33%	SD	2.31%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

**Page: 101**  
**Report Date:04/29/2009**

		Male				Female					
<b>#All Organs:</b>											
<b>Mesothelioma: Malignant</b>											
		2/50	(4%)	2/50	(4%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	6/150	(4%)	Mean 4%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 2.31%	
.....											
<b>#All Organs:</b>											
<b>Osteoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#All Organs:</b>											
<b>Osteosarcoma</b>											
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>#All Organs:</b>											
<b>Osteosarcoma or Osteoma</b>											
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>*Adrenal Cortex:</b>											
<b>Adenoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>*Adrenal Cortex:</b>											
<b>Carcinoma</b>											
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 102  
 Report Date:04/29/2009

		Male			Female			
<b>*Adrenal Medulla: Ganglioneuroma</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Adrenal Medulla: Hemangioma</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Adrenal Medulla: Pheochromocytoma Benign</b>								
Overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
<b>*Adrenal Medulla: Pheochromocytoma Complex</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Adrenal Medulla: Pheochromocytoma Malignant</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS</b>								
Overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 103  
 Report Date:04/29/2009

		Male				Female			
<b>#Bone:</b>									
<b>Chondrosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Bone:</b>									
<b>Chondrosarcoma or Chondroma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Bone:</b>									
<b>Chordoma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Bone:</b>									
<b>Osteoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Bone:</b>									
<b>Osteosarcoma</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	1/150	(0.67%)	Mean 0.67%
									SD 1.15%
.....									
<b>#Bone:</b>									
<b>Osteosarcoma or Osteoma</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	1/150	(0.67%)	Mean 0.67%
									SD 1.15%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 104  
 Report Date:04/29/2009

		Male				Female					
<b>*Brain:</b>											
<b>Astrocytoma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Ependymoma Benign</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Ependymoma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Glioma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Granular Cell Tumor Benign</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>*Brain:</b>											
<b>Medulloblastoma Mal</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 105  
 Report Date:04/29/2009

		Male				Female			
<b>*Brain:</b>									
<b>Meningioma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Brain:</b>									
<b>Meningioma: Benign, Malignant, NOS</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma Benign</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Brain:</b>									
<b>Osteosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%

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



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 106  
 Report Date:04/29/2009

		Male				Female					
<b>*Brain:</b>											
<b>Schwannoma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Adenoma</b>											
		1/50	(2%)	0/50	(0%)	5/50	(10%)	2/50	(4%)	1/50	(2%)
<b>Overall Incidence</b>	Total	6/150	(4%)	Mean 4%	SD 5.29%	Total	6/150	(4%)	Mean 4%	SD 2%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Carcinoma</b>											
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Carcinoma or Adenoma</b>											
		2/50	(4%)	0/50	(0%)	6/50	(12%)	2/50	(4%)	2/50	(4%)
<b>Overall Incidence</b>	Total	8/150	(5.33%)	Mean 5.33%	SD 6.11%	Total	7/150	(4.67%)	Mean 4.67%	SD 1.15%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Fibrosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Sarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 107  
 Report Date:04/29/2009

		Male				Female			
<b>*Clitoral/Preputial Gland: Squamous Cell Papilloma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Ear: Neural Crest Tumor</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Esophagus: Fibrosarcoma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Esophagus: Lipoma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Eye: Amelanotic Melanoma, Benign</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Eye: Melanoma Malignant</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

**Page: 108**  
**Report Date:04/29/2009**

	Male					Female				
<b>#Eye:</b>										
<b>Schwannoma Malignant</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%			0/150 (0%)	Mean 0%	SD 0%	
.....										
<b>#Harderian Gland:</b>										
<b>Carcinoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%			0/150 (0%)	Mean 0%	SD 0%	
.....										
<b>#Harderian Gland:</b>										
<b>Carcinoma or Adenoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%			0/150 (0%)	Mean 0%	SD 0%	
.....										
<b>*Heart:</b>										
<b>Schwannoma Benign</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%			0/150 (0%)	Mean 0%	SD 0%	
.....										
<b>*Heart:</b>										
<b>Schwannoma Malignant</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/150 (0%)	Mean 0%	SD 0%			1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....										
<b>#Intestine Large: Colon/Rectum:</b>										
<b>Adenoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/150 (0%)	Mean 0%	SD 0%			1/150 (0.67%)	Mean 0.67%	SD 1.15%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 109  
 Report Date:04/29/2009

		Male				Female			
<b>#Intestine Large: Colon/Rectum: Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Large: Colon/Rectum: Carcinoma or Adenoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
<b>#Intestine Large: Colon/Rectum: Hemangioma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Duodenum: Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Duodenum: Leiomyoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
<b>#Intestine Small: Jejunum: Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 110  
 Report Date:04/29/2009

		Male				Female			
<b>#Intestine Small: Jejunum: Granular Cell Tumor Malignant</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Jejunum: Leiomyoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Jejunum: Leiomyosarcoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified: Carcinoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified: Carcinoma or Adenoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 111  
 Report Date:04/29/2009

		Male				Female							
<b>#Intestine Small: Site Unspecified: Leiomyoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%			
.....													
<b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
<b>*Islets, Pancreatic: Adenoma</b>													
		2/50	(4%)	0/50	(0%)	2/50	(4%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%			
.....													
<b>*Islets, Pancreatic: Carcinoma</b>													
		1/50	(2%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	3/150	(2%)	Mean 2%	SD 2%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
<b>*Islets, Pancreatic: Carcinoma or Adenoma</b>													
		3/50	(6%)	0/50	(0%)	4/50	(8%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	7/150	(4.67%)	Mean 4.67%	SD 4.16%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%			
.....													
<b>*Kidney: Pelvis and Transitional Epithelium: Carcinoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 112  
 Report Date:04/29/2009

		Male				Female			
<b>*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Pelvis and Transitional Epithelium: Papilloma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Adenoma</b>									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Carcinoma or Adenoma</b>									
Overall Incidence	Total	1/50 (2%)	2/50 (4%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Hemangiosarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 113  
 Report Date:04/29/2009

		Male				Female			
<b>*Kidney: Renal Tubule: Lipoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Mesenchymal Tumor Benign</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Nephroblastoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Sarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver: Cholangioma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver: Hemangiosarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	

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



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 114  
 Report Date: 04/29/2009

		Male				Female							
<b>*Liver:</b>													
<b>Hepatocellular Adenoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 2.31%			
.....													
<b>*Liver:</b>													
<b>Hepatocellular Carcinoma</b>													
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
<b>*Liver:</b>													
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>													
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
<b>*Liver:</b>													
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>													
		0/50	(0%)	1/50	(2%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	2/150	(1.33%)	Mean 1.33%	SD 2.31%			
.....													
<b>*Liver:</b>													
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>													
		0/50	(0%)	1/50	(2%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	2/150	(1.33%)	Mean 1.33%	SD 2.31%			
.....													
<b>*Lung:</b>													
<b>Alveolar/Bronchiolar Adenoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%			

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 115  
 Report Date:04/29/2009

	Male					Female								
<b>*Lung:</b>														
<b>Alveolar/Bronchiolar Carcinoma</b>														
		1/50	(2%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>*Lung:</b>														
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>														
		1/50	(2%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	1/50	(2%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	3/150	(2%)	Mean	2%	SD	2%
.....														
<b>*Lung:</b>														
<b>Fibrosarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>*Lung:</b>														
<b>Hemangiosarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>*Lung:</b>														
<b>Sarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>*Lung:</b>														
<b>Squamous Cell Carcinoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 116  
 Report Date:04/29/2009

		Male				Female			
<b>#Lymph Node: Hemangiosarcoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mammary Gland: Adenolipoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mammary Gland: Adenoma</b>									
<b>Overall Incidence</b>	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	
.....									
<b>#Mammary Gland: Carcinoma</b>									
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
<b>#Mammary Gland: Carcinoma or Adenoma</b>									
<b>Overall Incidence</b>	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	Total	2/50 (4%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
		1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	6/150 (4%)	Mean 4%	SD 0%	
.....									
<b>#Mammary Gland: Fibroadenoma</b>									
<b>Overall Incidence</b>	Total	2/50 (4%)	2/50 (4%)	1/50 (2%)	Total	33/50 (66%)	32/50 (64%)	29/50 (58%)	29/50 (58%)
		5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	94/150 (62.67%)	Mean 62.67%	SD 4.16%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 117  
 Report Date:04/29/2009

	Male					Female								
<b>#Mammary Gland: Fibroma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
<b>#Mammary Gland: Fibroma, Fibroadenoma or Adenoma</b>														
		4/50	(8%)	2/50	(4%)	1/50	(2%)	33/50	(66%)	33/50	(66%)	30/50	(60%)	
<b>Overall Incidence</b>	Total	7/150	(4.67%)	Mean	4.67%	SD	3.06%	Total	96/150	(64%)	Mean	64%	SD	3.46%
<b>#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>														
		4/50	(8%)	2/50	(4%)	1/50	(2%)	35/50	(70%)	33/50	(66%)	30/50	(60%)	
<b>Overall Incidence</b>	Total	7/150	(4.67%)	Mean	4.67%	SD	3.06%	Total	98/150	(65.33%)	Mean	65.33%	SD	5.03%
<b>#Mesentery: Fibrosarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
<b>#Mesentery: Hemangiosarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
<b>#Mesentery: Lipoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 118  
 Report Date:04/29/2009

		Male				Female			
<b>#Mesentery:</b>									
<b>Rhabdomyosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Nose:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%
									SD 1.15%
.....									
<b>*Nose:</b>									
<b>Chondroma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Nose:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Papilloma Squamous or Papilloma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%
									SD 1.15%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 119  
 Report Date:04/29/2009

	Male					Female				
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>										
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%			1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....										
<b>#Oral Mucosa: Squamous Cell Carcinoma</b>										
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%			1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....										
<b>#Oral Mucosa: Squamous Cell Papilloma</b>										
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%			0/150 (0%)	Mean 0%	SD 0%	
.....										
<b>*Ovary: Cystadenoma</b>										
Overall Incidence						Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
							0/149 (0%)	Mean 0%	SD 0%	
.....										
<b>*Ovary: Granulosa Cell Tumor Benign</b>										
Overall Incidence						Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
							0/149 (0%)	Mean 0%	SD 0%	
.....										
<b>*Ovary: Granulosa Cell Tumor Malignant</b>										
Overall Incidence						Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
							0/149 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 120  
 Report Date:04/29/2009

		Male			Female			
<b>*Ovary:</b>								
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>								
			0/50 (0%)		0/50 (0%)	0/49 (0%)		
<b>Overall Incidence</b>		Total	0/149 (0%)		Mean 0%	SD 0%		
.....								
<b>*Ovary:</b>								
<b>Granulosa-Theca Tumor Benign</b>								
			0/50 (0%)		0/50 (0%)	0/49 (0%)		
<b>Overall Incidence</b>		Total	0/149 (0%)		Mean 0%	SD 0%		
.....								
<b>*Ovary:</b>								
<b>Granulosa-Theca Tumor Malignant</b>								
			0/50 (0%)		0/50 (0%)	0/49 (0%)		
<b>Overall Incidence</b>		Total	0/149 (0%)		Mean 0%	SD 0%		
.....								
<b>*Ovary:</b>								
<b>Tubulostromal Adenoma</b>								
			0/50 (0%)		0/50 (0%)	0/49 (0%)		
<b>Overall Incidence</b>		Total	0/149 (0%)		Mean 0%	SD 0%		
.....								
<b>*Pancreas:</b>								
<b>Adenoma</b>								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>*Pancreas:</b>								
<b>Carcinoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 121  
 Report Date:04/29/2009

		Male				Female					
<b>*Pancreas:</b>											
<b>Carcinoma or Adenoma</b>											
<b>Overall Incidence</b>	Total	0/50 1/150	(0%) (0.67%)	0/50 Mean 0.67%	(0%)	1/50 SD 1.15%	(2%)	0/50 Total	(0%) 0/150	0/50 Mean 0%	(0%) SD 0%
.....											
<b>*Pancreas:</b>											
<b>Mixed Tumor Benign</b>											
<b>Overall Incidence</b>	Total	0/50 0/150	(0%) (0%)	0/50 Mean 0%	(0%)	0/50 SD 0%	(0%)	0/50 Total	(0%) 0/150	0/50 Mean 0%	(0%) SD 0%
.....											
<b>*Pancreas:</b>											
<b>Mixed Tumor Malignant</b>											
<b>Overall Incidence</b>	Total	0/50 0/150	(0%) (0%)	0/50 Mean 0%	(0%)	0/50 SD 0%	(0%)	0/50 Total	(0%) 0/150	0/50 Mean 0%	(0%) SD 0%
.....											
<b>*Parathyroid Gland:</b>											
<b>Adenoma</b>											
<b>Overall Incidence</b>	Total	0/48 0/147	(0%) (0%)	0/50 Mean 0%	(0%)	0/49 SD 0%	(0%)	0/46 Total	(0%) 0/142	0/48 Mean 0%	(0%) SD 0%
.....											
<b>#Peripheral Nerve:</b>											
<b>Schwannoma Malignant</b>											
<b>Overall Incidence</b>	Total	0/50 0/150	(0%) (0%)	0/50 Mean 0%	(0%)	0/50 SD 0%	(0%)	0/50 Total	(0%) 0/150	0/50 Mean 0%	(0%) SD 0%
.....											
<b>#Peripheral Nerve:</b>											
<b>Schwannoma: Benign, Malignant, NOS</b>											
<b>Overall Incidence</b>	Total	0/50 0/150	(0%) (0%)	0/50 Mean 0%	(0%)	0/50 SD 0%	(0%)	0/50 Total	(0%) 0/150	0/50 Mean 0%	(0%) SD 0%

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



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 122  
 Report Date: 04/29/2009

		Male			Female		
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Adenoma</b>							
		11/50 (22%)	20/50 (40%)	15/50 (30%)	22/50 (44%)	16/50 (32%)	24/50 (48%)
<b>Overall Incidence</b>	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total 62/150 (41.33%)	Mean 41.33%	SD 8.33%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Carcinoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 3/150 (2%)	Mean 2%	SD 2%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Carcinoma or Adenoma</b>							
		11/50 (22%)	20/50 (40%)	15/50 (30%)	24/50 (48%)	16/50 (32%)	25/50 (50%)
<b>Overall Incidence</b>	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total 65/150 (43.33%)	Mean 43.33%	SD 9.87%
.....							
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>							
<b>Ganglioneuroma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>*Pituitary Gland: Pars Intermedia:</b>							
<b>Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
<b>*Pituitary Gland: Pars Intermedia:</b>							
<b>Carcinoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 123  
 Report Date:04/29/2009

		Male				Female			
<b>*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>*Prostate: Adenoma</b>									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%					
.....									
<b>*Prostate: Carcinoma or Adenoma</b>									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%					
.....									
<b>*Salivary Glands: Sarcoma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
.....									
<b>#Seminal Vesicle: Adenoma</b>									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%					
.....									
<b>#Skeletal Muscle: Fibrous Histiocytoma</b>									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 124  
 Report Date:04/29/2009

		Male				Female			
<b>#Skeletal Muscle: Hemangioma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle: Hemangiosarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle: Lipoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle: Rhabdomyosarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle: Sarcoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 125  
 Report Date:04/29/2009

	Male					Female					
<b>#Skin:</b>											
<b>Basal Cell Adenoma</b>											
		1/50	(2%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	3/150	(2%)	Mean 2%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	
.....											
<b>#Skin:</b>											
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>											
		1/50	(2%)	1/50	(2%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	3/150	(2%)	Mean 2%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	
.....											
<b>#Skin:</b>											
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>											
		1/50	(2%)	1/50	(2%)	1/50	(2%)	2/50	(4%)	1/50	(2%)
<b>Overall Incidence</b>	Total	3/150	(2%)	Mean 2%	SD 0%	Total	3/150	(2%)	Mean 2%	SD 2%	
.....											
<b>#Skin:</b>											
<b>Basal Cell Carcinoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>											
		1/50	(2%)	1/50	(2%)	1/50	(2%)	2/50	(4%)	1/50	(2%)
<b>Overall Incidence</b>	Total	3/150	(2%)	Mean 2%	SD 0%	Total	3/150	(2%)	Mean 2%	SD 2%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 126  
 Report Date:04/29/2009

		Male				Female			
<b>#Skin:</b>									
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>									
		10/50 (20%)	2/50 (4%)	4/50 (8%)		4/50 (8%)	3/50 (6%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	16/150 (10.67%)	Mean 10.67%	SD 8.33%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	
.....									
<b>#Skin:</b>									
<b>Fibroma</b>									
		6/50 (12%)	2/50 (4%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	13/150 (8.67%)	Mean 8.67%	SD 4.16%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
<b>#Skin:</b>									
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>									
		7/50 (14%)	3/50 (6%)	6/50 (12%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
<b>#Skin:</b>									
<b>Fibrosarcoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>									
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	3/150 (2%)	Mean 2%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Fibrous Histiocytoma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 127  
 Report Date:04/29/2009

		Male				Female					
<b>#Skin:</b>											
<b>Hemangioma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Hemangiosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Keratoacanthoma</b>											
		8/50	(16%)	0/50	(0%)	2/50	(4%)	2/50	(4%)	0/50	(0%)
<b>Overall Incidence</b>	Total	10/150	(6.67%)	Mean 6.67%	SD 8.33%	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	
.....											
<b>#Skin:</b>											
<b>Lipoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Liposarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Skin:</b>											
<b>Neural Crest Tumor</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 128  
 Report Date:04/29/2009

		Male			Female			
<b>#Skin:</b>								
<b>Neural Crest Tumor, Malignant</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Neurofibroma or Schwannoma benign</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>#Skin:</b>								
<b>Sarcoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Schwannoma Benign</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 129  
 Report Date:04/29/2009

		Male				Female								
<b>#Skin:</b>														
<b>Schwannoma Malignant</b>														
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Skin:</b>														
<b>Squamous Cell Carcinoma</b>														
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Skin:</b>														
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>														
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Skin:</b>														
<b>Squamous Cell Papilloma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Skin:</b>														
<b>Squamous Cell Papilloma or Papilloma</b>														
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Skin:</b>														
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>														
		9/50	(18%)	1/50	(2%)	3/50	(6%)	2/50	(4%)	3/50	(6%)			
<b>Overall Incidence</b>	Total	13/150	(8.67%)	Mean	8.67%	SD	8.33%	Total	5/150	(3.33%)	Mean	3.33%	SD	3.06%

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



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

**Page: 130**  
**Report Date:04/29/2009**

		Male				Female								
<b>#Skin:</b>														
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>														
		9/50	(18%)	0/50	(0%)	2/50	(4%)	2/50	(4%)	3/50	(6%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	11/150	(7.33%)	Mean	7.33%	SD	9.45%	Total	5/150	(3.33%)	Mean	3.33%	SD	3.06%
.....														
<b>#Skin:</b>														
<b>Trichoepithelioma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Skin: Sebaceous Gland:</b>														
<b>Adenoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Skin: Sebaceous Gland:</b>														
<b>Carcinoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Skin: Sebaceous Gland:</b>														
<b>Carcinoma or Adenoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Spinal Cord:</b>														
<b>Astrocytoma Benign</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 131  
 Report Date:04/29/2009

		Male				Female					
<b>#Spinal Cord:</b>											
<b>Astrocytoma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Spinal Cord:</b>											
<b>Glioma Malignant</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
<b>*Spleen:</b>											
<b>Fibrosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Spleen:</b>											
<b>Fibrous Histiocytoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Spleen:</b>											
<b>Hemangioma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Spleen:</b>											
<b>Hemangiosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 132  
 Report Date:04/29/2009

		Male				Female								
<b>*Spleen:</b>														
<b>Leiomyosarcoma</b>														
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>*Spleen:</b>														
<b>Sarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Stomach, Forestomach:</b>														
<b>Leiomyosarcoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
<b>#Stomach, Forestomach:</b>														
<b>Squamous Cell Carcinoma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Stomach, Forestomach:</b>														
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
<b>#Stomach, Forestomach:</b>														
<b>Squamous Cell Papilloma</b>														
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 133  
 Report Date:04/29/2009

	Male					Female					
<b>#Stomach, Glandular: Lipoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>#Stomach, Glandular: Sarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
<b>*Testes: Adenoma</b>											
		44/50	(88%)	45/50	(90%)	48/50	(96%)				
<b>Overall Incidence</b>	Total	137/150	(91.33%)	Mean 91.33%	SD 4.16%						
.....											
<b>*Thymus: Sarcoma</b>											
		0/49	(0%)	0/50	(0%)	0/48	(0%)	0/48	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/147	(0%)	Mean 0%	SD 0%	Total	0/144	(0%)	Mean 0%	SD 0%	
.....											
<b>*Thymus: Thymoma Benign</b>											
		0/49	(0%)	0/50	(0%)	0/48	(0%)	0/48	(0%)	1/48	(2%)
<b>Overall Incidence</b>	Total	0/147	(0%)	Mean 0%	SD 0%	Total	1/144	(0.69%)	Mean 0.69%	SD 1.2%	
.....											
<b>*Thymus: Thymoma Malignant</b>											
		0/49	(0%)	0/50	(0%)	0/48	(0%)	1/48	(2%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/147	(0%)	Mean 0%	SD 0%	Total	1/144	(0.69%)	Mean 0.69%	SD 1.2%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 134  
 Report Date:04/29/2009

		Male			Female			
<b>*Thymus:</b>								
<b>Thymoma NOS</b>								
		0/49 (0%)	0/50 (0%)	0/48 (0%)	0/48 (0%)	0/48 (0%)	0/48 (0%)	
<b>Overall Incidence</b>	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
.....								
<b>*Thymus:</b>								
<b>Thymoma: Benign, Malignant, NOS</b>								
		0/49 (0%)	0/50 (0%)	0/48 (0%)	0/48 (0%)	1/48 (2%)	1/48 (2%)	
<b>Overall Incidence</b>	Total	0/147 (0%)	Mean 0%	SD 0%	Total	2/144 (1.39%)	Mean 1.39%	SD 1.2%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Adenoma</b>								
		6/50 (12%)	11/50 (22%)	1/50 (2%)	5/50 (10%)	6/50 (12%)	11/50 (22%)	
<b>Overall Incidence</b>	Total	18/150 (12%)	Mean 12%	SD 10%	Total	22/150 (14.67%)	Mean 14.67%	SD 6.43%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma</b>								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
<b>*Thyroid Gland: C-Cell:</b>								
<b>Carcinoma or Adenoma</b>								
		6/50 (12%)	11/50 (22%)	1/50 (2%)	5/50 (10%)	6/50 (12%)	12/50 (24%)	
<b>Overall Incidence</b>	Total	18/150 (12%)	Mean 12%	SD 10%	Total	23/150 (15.33%)	Mean 15.33%	SD 7.57%
.....								
<b>*Thyroid Gland: Follicular Cell:</b>								
<b>Adenoma</b>								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
<b>Overall Incidence</b>	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 135  
 Report Date:04/29/2009

		Male				Female			
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	2/50 (4%)	Total	0/50 (0%)	0/50 (0%)	2/50 (4%)	
		4/150 (2.67%)	Mean 2.67%	SD 1.15%		2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	3/50 (6%)	Total	0/50 (0%)	0/50 (0%)	2/50 (4%)	
		5/150 (3.33%)	Mean 3.33%	SD 2.31%		2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
<b>#Tissue NOS: Lipoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tissue NOS: Paraganglioma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tissue NOS: Schwannoma Malignant</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tongue: Squamous Cell Carcinoma</b>									
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 136  
 Report Date:04/29/2009

		Male				Female			
<b>#Tongue:</b>									
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Tongue:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Tooth:</b>									
<b>Adamantinoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>#Tooth:</b>									
<b>Odontoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Urinary Bladder:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
.....									
<b>*Urinary Bladder:</b>									
<b>Carcinoma or Papilloma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 137  
 Report Date:04/29/2009

		Male			Female			
<b>*Urinary Bladder: Hemangiosarcoma</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Urinary Bladder: Leiomyosarcoma</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>*Urinary Bladder: Papilloma</b>								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>#Uterus: Adenoma</b>								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>#Uterus: Carcinoma</b>								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
<b>#Uterus: Deciduoma Benign</b>								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 138  
 Report Date:04/29/2009

	Male		Female
<b>#Uterus:</b>			
<b>Hemangioma</b>			
		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0% SD 0%
.....			
<b>#Uterus:</b>			
<b>Hemangiosarcoma</b>			
		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0% SD 0%
.....			
<b>#Uterus:</b>			
<b>Leiomyoma</b>			
		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0% SD 0%
.....			
<b>#Uterus:</b>			
<b>Leiomyosarcoma</b>			
		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0% SD 0%
.....			
<b>#Uterus:</b>			
<b>Polyp Stromal</b>			
		7/50 (14%)	8/50 (16%)
<b>Overall Incidence</b>	Total	23/150 (15.33%)	Mean 15.33% SD 1.15%
.....			
<b>#Uterus:</b>			
<b>Sarcoma Stromal</b>			
		0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0% SD 0%

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

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F344  
 Length of Study: CHRONIC

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

Page: 139  
 Report Date:04/29/2009

		Male			Female		
<b>#Uterus:</b>							
<b>Sarcoma Stromal or Polyp Stromal</b>							
			7/50 (14%)		8/50 (16%)		8/50 (16%)
<b>Overall Incidence</b>		Total	23/150 (15.33%)		Mean 15.33%		SD 1.15%
.....							
<b>#Uterus:</b>							
<b>Schwannoma Malignant</b>							
			1/50 (2%)		0/50 (0%)		0/50 (0%)
<b>Overall Incidence</b>		Total	1/150 (0.67%)		Mean 0.67%		SD 1.15%
.....							
<b>#Vagina:</b>							
<b>Polyp</b>							
			0/50 (0%)		0/50 (0%)		0/50 (0%)
<b>Overall Incidence</b>		Total	0/150 (0%)		Mean 0%		SD 0%
.....							
<b>#Vagina:</b>							
<b>Sarcoma</b>							
			0/50 (0%)		0/50 (0%)		0/50 (0%)
<b>Overall Incidence</b>		Total	0/150 (0%)		Mean 0%		SD 0%
.....							
<b>#Zymbal's Gland:</b>							
<b>Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
<b>#Zymbal's Gland:</b>							
<b>Carcinoma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
							SD 0%

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

Version: May2009  
Contract/Lab: All Laboratories  
Species: RATS  
Strain: F344  
Length of Study: CHRONIC

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

**Page: 140**  
**Report Date:**04/29/2009

---

	Male					Female				
<b>#Zymbal's Gland:</b>										
<b>Carcinoma or Adenoma</b>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

---

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