

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

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle 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
Female							
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.

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

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

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

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		Male			Female			
*Adrenal Medulla: Ganglioneuroma								
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%
*Adrenal Medulla: Hemangioma								
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%
*Adrenal Medulla: Pheochromocytoma Benign								
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%
*Adrenal Medulla: Pheochromocytoma Complex								
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%
*Adrenal Medulla: Pheochromocytoma Malignant								
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%
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS								
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%

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

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

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

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

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		Male				Female			
*Clitoral/Preputial Gland: Squamous Cell Papilloma									
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%	
.....									
#Ear: Neural Crest Tumor									
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%	
.....									
#Esophagus: Fibrosarcoma									
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%	
.....									
#Esophagus: Lipoma									
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%	
.....									
#Eye: Amelanotic Melanoma, Benign									
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%	
.....									
#Eye: Melanoma Malignant									
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%	

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

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Vehicle: WATER

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Report Date:04/29/2009

		Male				Female			
#Intestine Large: Colon/Rectum: Carcinoma									
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%	
.....									
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma									
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%	
.....									
#Intestine Large: Colon/Rectum: Hemangioma									
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%	
.....									
#Intestine Small: Duodenum: Carcinoma									
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%	
.....									
#Intestine Small: Duodenum: Leiomyoma									
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%	
.....									
#Intestine Small: Jejunum: Carcinoma									
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

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 Report Date:04/29/2009

		Male				Female			
#Intestine Small: Jejunum: Granular Cell Tumor Malignant									
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%	
.....									
#Intestine Small: Jejunum: Leiomyoma									
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%	
.....									
#Intestine Small: Jejunum: Leiomyosarcoma									
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%	
.....									
#Intestine Small: Site Unspecified: Carcinoma									
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%	
.....									
#Intestine Small: Site Unspecified: Carcinoma or Adenoma									
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%	
.....									
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant									
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

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

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 Report Date:04/29/2009

		Male				Female			
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma									
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%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Papilloma									
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%	
.....									
*Kidney: Renal Tubule: Adenoma									
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%	
.....									
*Kidney: Renal Tubule: Carcinoma									
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%	
.....									
*Kidney: Renal Tubule: Carcinoma or Adenoma									
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%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
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

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

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

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 Report Date:04/29/2009

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

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

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

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

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

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 Report Date:04/29/2009

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

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

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

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		Male				Female			
#Skeletal Muscle: Hemangioma									
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%	
.....									
#Skeletal Muscle: Hemangiosarcoma									
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%	
.....									
#Skeletal Muscle: Lipoma									
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%	
.....									
#Skeletal Muscle: Rhabdomyosarcoma									
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%	
.....									
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma									
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%	
.....									
#Skeletal Muscle: Sarcoma									
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

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

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

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

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

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

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

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

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

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 Report Date:04/29/2009

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

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

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		Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	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%		
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	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%		
.....									
#Tissue NOS: Lipoma									
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%		
.....									
#Tissue NOS: Paraganglioma									
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%		
.....									
#Tissue NOS: Schwannoma Malignant									
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%		
.....									
#Tongue: Squamous Cell Carcinoma									
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

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

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

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

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