

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

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

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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
<b>Male</b>							
Southern Research Institute	059902407	02/03/03	729	50(3)	21(661)	518.7	Androstenedione
Southern Research Institute	059903705	06/09/03	729	50(3)	27(662)	523.0	alpha/beta Thujone mixture
<b>Female</b>							
Southern Research Institute	059902407	02/03/03	729	50(5)	38(710)	356.5	Androstenedione
Southern Research Institute	059903705	06/09/03	730	50(5)	35(689)	335.4	alpha/beta Thujone mixture

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		Male			Female			
<b>#All Organs:</b>								
<b>Benign Tumors</b>								
		47/50 (94%)	44/50 (88%)		44/50 (88%)	46/50 (92%)		
<b>Overall Incidence</b>	Total	91/100 (91%)	Mean 91%	SD 4.24%	Total	90/100 (90%)	Mean 90%	SD 2.83%
.....								
<b>#All Organs:</b>								
<b>Malignant Tumors</b>								
		34/50 (68%)	31/50 (62%)		10/50 (20%)	20/50 (40%)		
<b>Overall Incidence</b>	Total	65/100 (65%)	Mean 65%	SD 4.24%	Total	30/100 (30%)	Mean 30%	SD 14.14%
.....								
<b>#All Organs:</b>								
<b>Malignant and Benign Tumors</b>								
		49/50 (98%)	48/50 (96%)		46/50 (92%)	49/50 (98%)		
<b>Overall Incidence</b>	Total	97/100 (97%)	Mean 97%	SD 1.41%	Total	95/100 (95%)	Mean 95%	SD 4.24%
.....								
<b>#All Organs:</b>								
<b>Hemangioma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#All Organs:</b>								
<b>Hemangiosarcoma</b>								
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#All Organs:</b>								
<b>Hemangiosarcoma or Hemangioma</b>								
		1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (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			
<b>#All Organs:</b>									
<b>Histiocytic Sarcoma</b>									
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 0%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
<b>#All Organs:</b>									
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>									
		26/50	(52%)	22/50	(44%)	5/50	(10%)	10/50	(20%)
<b>Overall Incidence</b>	Total	48/100	(48%)	Mean 48%	SD 5.66%	Total	15/100	(15%)	Mean 15%
									SD 7.07%
<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%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
<b>#All Organs:</b>									
<b>Mesothelioma: Benign</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
<b>#All Organs:</b>									
<b>Mesothelioma: Benign, Malignant, NOS</b>									
		1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%

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		Male				Female			
<b>#All Organs:</b>									
<b>Mesothelioma: Malignant</b>									
		1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	3/100	(3%)	Mean 3%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#All Organs:</b>									
<b>Osteoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#All Organs:</b>									
<b>Osteosarcoma</b>									
		1/50	(2%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
<b>#All Organs:</b>									
<b>Osteosarcoma or Osteoma</b>									
		1/50	(2%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
<b>*Adrenal Cortex:</b>									
<b>Adenoma</b>									
		3/50	(6%)	1/50	(2%)	0/50	(0%)	1/47	(2%)
<b>Overall Incidence</b>	Total	4/100	(4%)	Mean 4%	SD 2.83%	Total	1/97	(1.03%)	Mean 1.06%
									SD 1.5%
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/47	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/97	(0%)	Mean 0%
									SD 0%

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		Male				Female			
<b>*Adrenal Medulla: Ganglioneuroma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla: Hemangioma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Benign</b>									
		7/50 (14%)	6/50 (12%)		3/50 (6%)	2/48 (4%)			
<b>Overall Incidence</b>	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	5/98 (5.1%)	Mean 5.08%	SD 1.3%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Complex</b>									
		1/50 (2%)	0/50 (0%)		1/50 (2%)	1/48 (2%)			
<b>Overall Incidence</b>	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/98 (2.04%)	Mean 2.04%	SD 0.06%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Malignant</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
		8/50 (16%)	6/50 (12%)		4/50 (8%)	3/48 (6%)			
<b>Overall Incidence</b>	Total	14/100 (14%)	Mean 14%	SD 2.83%	Total	7/98 (7.14%)	Mean 7.13%	SD 1.24%	

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

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		Male				Female			
<b>*Brain:</b>									
<b>Ependymoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma Benign</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>*Brain:</b>									
<b>Glioma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
<b>*Brain:</b>									
<b>Granular Cell Tumor Benign</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(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	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

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

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		Male				Female					
<b>*Brain:</b>											
<b>Oligodendroglioma Malignant</b>											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
<b>*Brain:</b>											
<b>Osteosarcoma</b>											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Brain:</b>											
<b>Schwannoma Malignant</b>											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Adenoma</b>											
		3/50	(6%)	2/49	(4%)			12/50	(24%)	12/50	(24%)
<b>Overall Incidence</b>	Total	5/99	(5.05%)	Mean 5.04%	SD 1.36%	Total	24/100	(24%)	Mean 24%	SD 0%	
.....											
<b>*Clitoral/Preputial Gland:</b>											
<b>Carcinoma</b>											
		0/50	(0%)	1/49	(2%)			1/50	(2%)	2/50	(4%)
<b>Overall Incidence</b>	Total	1/99	(1.01%)	Mean 1.02%	SD 1.44%	Total	3/100	(3%)	Mean 3%	SD 1.41%	

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		Male			Female		
<b>*Clitoral/Preputial Gland: Carcinoma or Adenoma</b>							
		3/50 (6%)	3/49 (6%)		13/50 (26%)	14/50 (28%)	
<b>Overall Incidence</b>	Total	6/99 (6.06%)	Mean 6.06%	SD 0.09%	Total	27/100 (27%)	Mean 27% SD 1.41%
.....							
<b>*Clitoral/Preputial Gland: Sarcoma</b>							
		0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1% SD 1.41%
.....							
<b>#Ear: Neural Crest Tumor</b>							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
<b>#Esophagus: Lipoma</b>							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
<b>#Eye: Melanoma Benign</b>							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%
.....							
<b>#Eye: Melanoma Malignant</b>							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0% SD 0%

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		Male				Female			
<b>#Eye:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Harderian Gland:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Harderian Gland:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Harderian Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>*Heart:</b>									
<b>Schwannoma Benign</b>									
		0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>*Heart:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(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			
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Hemangioma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Intestine Small: Duodenum:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Intestine Small: Duodenum:</b>									
<b>Leiomyoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Intestine Small: Duodenum:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%

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

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

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
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		Male				Female			
<b>#Intestine Small: Ileum:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Granular Cell Tumor Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Intestine Small: Site Unspecified:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

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

#: Denominator is number of animals necropsied

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

**Toxicology Data Management System**  
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		Male				Female				
<b>#Intestine Small: Site Unspecified: Carcinoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			
.....										
<b>#Intestine Small: Site Unspecified: Carcinoma or Adenoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			
.....										
<b>#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			
.....										
<b>#Intestine Small: Site Unspecified: Leiomyoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			
.....										
<b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			
.....										
<b>#Intestine Small: Site Unspecified: Schwannoma Malignant</b>										
<b>Overall Incidence</b>	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
		0/100 (0%)					0/100 (0%)			

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

#: Denominator is number of animals necropsied

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

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		Male				Female					
<b>*Islets, Pancreatic:</b>											
<b>Adenoma</b>											
		4/50	(8%)	1/50	(2%)			1/50	(2%)	1/49	(2%)
<b>Overall Incidence</b>	Total	5/100	(5%)	Mean 5%	SD 4.24%	Total	2/99	(2.02%)	Mean 2.02%	SD 0.03%	
.....											
<b>*Islets, Pancreatic:</b>											
<b>Carcinoma</b>											
		0/50	(0%)	2/50	(4%)			1/50	(2%)	0/49	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	1/99	(1.01%)	Mean 1%	SD 1.41%	
.....											
<b>*Islets, Pancreatic:</b>											
<b>Carcinoma or Adenoma</b>											
		4/50	(8%)	3/50	(6%)			2/50	(4%)	1/49	(2%)
<b>Overall Incidence</b>	Total	7/100	(7%)	Mean 7%	SD 1.41%	Total	3/99	(3.03%)	Mean 3.02%	SD 1.39%	
.....											
<b>*Kidney: Pelvis and Transitional Epithelium:</b>											
<b>Carcinoma</b>											
		0/49	(0%)	0/48	(0%)			0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0%	SD 0%	
.....											
<b>*Kidney: Pelvis and Transitional Epithelium:</b>											
<b>Carcinoma or Adenoma</b>											
		0/49	(0%)	0/48	(0%)			0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0%	SD 0%	
.....											
<b>*Kidney: Pelvis and Transitional Epithelium:</b>											
<b>Papilloma</b>											
		0/49	(0%)	0/48	(0%)			0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

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

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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 Vehicle: METHYLCELLULOSE

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		Male				Female			
<b>*Kidney: Renal Tubule: Adenoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule: Carcinoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule: Carcinoma or Adenoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule: Hemangiosarcoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule: Lipoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%
.....									
<b>*Kidney: Renal Tubule: Mesenchymal Tumor Benign</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0% SD 0%

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

#: Denominator is number of animals necropsied

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

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

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		Male				Female			
<b>*Kidney: Renal Tubule:</b>									
<b>Mesenchymal Tumor Malignant</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	1/44	(2%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	1/94	(1.06%)	Mean 1.14%
									SD 1.61%
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Nephroblastoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0%
									SD 0%
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>Sarcoma</b>									
		0/49	(0%)	0/48	(0%)	0/50	(0%)	0/44	(0%)
<b>Overall Incidence</b>	Total	0/97	(0%)	Mean 0%	SD 0%	Total	0/94	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Cholangioma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Hemangiosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Hepatocellular Adenoma</b>									
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									

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

#: Denominator is number of animals necropsied



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

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

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		Male				Female			
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>									
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>									
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Liver:</b>									
<b>Ito Cell Tumor Benign</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Adenoma</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									

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

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

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: GAVAGE  
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		Male				Female					
<b>*Lung:</b>											
<b>Alveolar/Bronchiolar Carcinoma</b>											
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Lung:</b>											
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>											
		0/50	(0%)	2/50	(4%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Lung:</b>											
<b>Fibrosarcoma</b>											
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>*Lung:</b>											
<b>Hemangiosarcoma</b>											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
<b>#Lymph Node:</b>											
<b>Hemangiosarcoma</b>											
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

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

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		Male				Female			
<b>#Mammary Gland:</b>									
<b>Adenolipoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	2/100	(2%)	Mean 2%
									SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	2/50	(4%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	4/100	(4%)	Mean 4%
									SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50	(0%)	0/50	(0%)	3/50	(6%)	3/50	(6%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	6/100	(6%)	Mean 6%
									SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Fibroadenoma</b>									
		2/50	(4%)	3/50	(6%)	35/50	(70%)	26/50	(52%)
<b>Overall Incidence</b>	Total	5/100	(5%)	Mean 5%	SD 1.41%	Total	61/100	(61%)	Mean 61%
									SD 12.73%
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									

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

#: Denominator is number of animals necropsied

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

**Toxicology Data Management System**  
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		Male				Female			
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma or Adenoma</b>									
		3/50 (6%)	3/50 (6%)			36/50 (72%)	28/50 (56%)		
<b>Overall Incidence</b>	Total	6/100 (6%)	Mean 6%	SD 0%	Total	64/100 (64%)	Mean 64%	SD 11.31%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>									
		3/50 (6%)	3/50 (6%)			37/50 (74%)	30/50 (60%)		
<b>Overall Incidence</b>	Total	6/100 (6%)	Mean 6%	SD 0%	Total	67/100 (67%)	Mean 67%	SD 9.9%	
.....									
<b>#Mesentery:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

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

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

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

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

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	Male				Female			
<b>#Oral Mucosa:</b>								
<b>Squamous Cell Papilloma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>*Ovary:</b>								
<b>Cystadenoma</b>								
					0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>					Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>*Ovary:</b>								
<b>Fibrosarcoma</b>								
					0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>					Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>*Ovary:</b>								
<b>Granulosa Cell Tumor Benign</b>								
					0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>					Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>*Ovary:</b>								
<b>Granulosa Cell Tumor Malignant</b>								
					0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>					Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
<b>*Ovary:</b>								
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>								
					0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>					Total	1/100 (1%)	Mean 1%	SD 1.41%

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

#: Denominator is number of animals necropsied

Version: May2011  
 Contract/Lab: All Laboratories  
 Species: RATS  
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		Male			Female		
<b>*Ovary:</b>							
<b>Granulosa-Theca Tumor Benign</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)		Mean 0%		SD 0%
.....							
<b>*Ovary:</b>							
<b>Granulosa-Theca Tumor Malignant</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)		Mean 0%		SD 0%
.....							
<b>*Ovary:</b>							
<b>Schwannoma Malignant</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)		Mean 0%		SD 0%
.....							
<b>*Ovary:</b>							
<b>Tubulostromal Adenoma</b>							
			1/50 (2%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	1/100 (1%)		Mean 1%		SD 1.41%
.....							
<b>*Pancreas:</b>							
<b>Adenoma</b>							
		3/50 (6%)	0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/99 (0%)	Mean 0%
							SD 0%
.....							
<b>*Pancreas:</b>							
<b>Carcinoma</b>							
		0/50 (0%)	0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%
							SD 0%
.....							

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

#: Denominator is number of animals necropsied

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

**Toxicology Data Management System**  
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 Route: GAVAGE  
 Vehicle: METHYLCELLULOSE

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		Male				Female			
<b>*Pancreas:</b>									
<b>Carcinoma or Adenoma</b>									
		3/50	(6%)	0/50	(0%)	0/50	(0%)	0/49	(0%)
<b>Overall Incidence</b>	Total	3/100	(3%)	Mean 3%	SD 4.24%	Total	0/99	(0%)	Mean 0%
									SD 0%
.....									
<b>*Pancreas:</b>									
<b>Mixed Tumor Benign</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/49	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/99	(0%)	Mean 0%
									SD 0%
.....									
<b>*Pancreas:</b>									
<b>Mixed Tumor Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/99	(0%)	Mean 0%
									SD 0%
.....									
<b>*Parathyroid Gland:</b>									
<b>Adenoma</b>									
		0/48	(0%)	0/48	(0%)	0/49	(0%)	0/47	(0%)
<b>Overall Incidence</b>	Total	0/96	(0%)	Mean 0%	SD 0%	Total	0/96	(0%)	Mean 0%
									SD 0%
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Adenoma</b>									
		19/50	(38%)	24/50	(48%)	19/50	(38%)	25/50	(50%)
<b>Overall Incidence</b>	Total	43/100	(43%)	Mean 43%	SD 7.07%	Total	44/100	(44%)	Mean 44%
									SD 8.49%
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	1/100	(1%)	Mean 1%
									SD 1.41%
.....									

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

#: Denominator is number of animals necropsied



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		Male				Female			
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>  Carcinoma or Adenoma</b>									
		19/50 (38%)	24/50 (48%)		19/50 (38%)	26/50 (52%)			
<b>Overall Incidence</b>	Total	43/100 (43%)	Mean 43%	SD 7.07%	Total	45/100 (45%)	Mean 45%	SD 9.9%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>  Ganglioneuroma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>  Adenoma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>  Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
.....									
<b>*Pituitary Gland: Pars Nervosa:</b>									
<b>  Craniopharyngioma</b>									
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
<b>*Prostate:</b>									
<b>  Adenoma</b>									
		0/50 (0%)	2/50 (4%)						
<b>Overall Incidence</b>	Total	2/100 (2%)	Mean 2%	SD 2.83%					

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

#: Denominator is number of animals necropsied

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**Toxicology Data Management System**  
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		Male				Female			
<b>*Prostate:</b>									
<b>  Carcinoma or Adenoma</b>									
		0/50	(0%)	2/50	(4%)				
<b>Overall Incidence</b>	Total	2/100	(2%)	Mean 2%	SD 2.83%				
.....									
<b>*Salivary Glands:</b>									
<b>  Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Salivary Glands:</b>									
<b>  Carcinoma or Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Salivary Glands:</b>									
<b>  Sarcoma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>*Salivary Glands:</b>									
<b>  Schwannoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Seminal Vesicle:</b>									
<b>  Adenoma</b>									
		0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	0/100	(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			
<b>#Skeletal Muscle:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Skeletal Muscle:</b>									
<b>Hemangiosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Skeletal Muscle:</b>									
<b>Rhabdomyosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Skeletal Muscle:</b>									
<b>Rhabdomyosarcoma or Rhabdomyoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	1/100	(1%)	Mean 1% SD 1.41%

\*: Denominator is number of animals with tissues examined microscopically  
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	Male				Female			
<b>#Skin:</b>								
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>								
		0/50 (0%)	3/50 (6%)		0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
<b>#Skin:</b>								
<b>Basal Cell Carcinoma</b>								
		1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
<b>#Skin:</b>								
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>								
		1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
.....								
<b>#Skin:</b>								
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>								
		1/50 (2%)	4/50 (8%)		0/50 (0%)	2/50 (4%)		
<b>Overall Incidence</b>	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%
.....								
<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>								
		5/50 (10%)	9/50 (18%)		0/50 (0%)	2/50 (4%)		
<b>Overall Incidence</b>	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	2/100 (2%)	Mean 2%	SD 2.83%
.....								
<b>#Skin:</b>								
<b>Fibroma</b>								
		5/50 (10%)	11/50 (22%)		3/50 (6%)	2/50 (4%)		
<b>Overall Incidence</b>	Total	16/100 (16%)	Mean 16%	SD 8.49%	Total	5/100 (5%)	Mean 5%	SD 1.41%

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

#: Denominator is number of animals necropsied

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	Male				Female			
<b>#Skin:</b>								
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		6/50 (12%)	16/50 (32%)		3/50 (6%)	2/50 (4%)		
<b>Overall Incidence</b>	Total	22/100 (22%)	Mean 22%	SD 14.14%	Total	5/100 (5%)	Mean 5%	SD 1.41%
.....								
<b>#Skin:</b>								
<b>Fibrosarcoma</b>								
		1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		1/50 (2%)	6/50 (12%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	7/100 (7%)	Mean 7%	SD 7.07%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Fibrous Histiocytoma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Hemangioma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Hemangiosarcoma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

Version: May2011  
 Contract/Lab: All Laboratories  
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		Male				Female			
<b>#Skin:</b>									
<b>Keratoacanthoma</b>									
		3/50	(6%)	5/50	(10%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	8/100	(8%)	Mean 8%	SD 2.83%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Skin:</b>									
<b>Lipoma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Skin:</b>									
<b>Liposarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%
.....									
<b>#Skin:</b>									
<b>Neural Crest Tumor, Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
									SD 0%

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

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

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 Tumor Incidence for Selected Control Animal Groups  
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 Vehicle: METHYLCELLULOSE

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	Male				Female			
<b>#Skin:</b>								
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Sarcoma</b>								
		0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Schwannoma Benign</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Schwannoma Malignant</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Squamous Cell Carcinoma</b>								
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

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

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

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		Male				Female					
<b>#Skin:</b>											
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>											
<b>Overall Incidence</b>	Total	1/50 (2%)	2/100 (2%)	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	1/50 (2%)	Mean 1%	SD 1.41%
.....											
<b>#Skin:</b>											
<b>Squamous Cell Papilloma</b>											
<b>Overall Incidence</b>	Total	1/50 (2%)	1/100 (1%)	0/50 (0%)	Mean 1%	SD 1.41%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
.....											
<b>#Skin:</b>											
<b>Squamous Cell Papilloma or Papilloma</b>											
<b>Overall Incidence</b>	Total	1/50 (2%)	1/100 (1%)	0/50 (0%)	Mean 1%	SD 1.41%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
.....											
<b>#Skin:</b>											
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>											
<b>Overall Incidence</b>	Total	4/50 (8%)	9/100 (9%)	5/50 (10%)	Mean 9%	SD 1.41%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
.....											
<b>#Skin:</b>											
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>											
<b>Overall Incidence</b>	Total	4/50 (8%)	9/100 (9%)	5/50 (10%)	Mean 9%	SD 1.41%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%
.....											
<b>#Skin:</b>											
<b>Trichoepithelioma</b>											
<b>Overall Incidence</b>	Total	0/50 (0%)	2/100 (2%)	2/50 (4%)	Mean 2%	SD 2.83%	Total	0/50 (0%)	0/50 (0%)	Mean 0%	SD 0%

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



Version: May2011  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: F 344/N  
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		Male				Female			
<b>#Skin: Sebaceous Gland:</b>									
<b>Adenoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(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%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Spinal Cord:</b>									
<b>Astrocytoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Spinal Cord:</b>									
<b>Glioma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>*Spleen:</b>									
<b>Fibrosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/98	(0%)	Mean 0% SD 0%

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

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

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 Tumor Incidence for Selected Control Animal Groups  
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 Vehicle: METHYLCELLULOSE

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		Male				Female			
<b>*Spleen:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/98	(0%)	Mean 0%
.....									
<b>*Spleen:</b>									
<b>Hemangiosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/98	(0%)	Mean 0%
.....									
<b>*Spleen:</b>									
<b>Leiomyosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/98	(0%)	Mean 0%
.....									
<b>*Spleen:</b>									
<b>Sarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/98	(0%)	Mean 0%
.....									
<b>#Stomach, Forestomach:</b>									
<b>Leiomyosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0%

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

#: Denominator is number of animals necropsied

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

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

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

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

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 Route: GAVAGE  
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		Male				Female			
<b>*Testes:</b>									
<b>Adenoma</b>									
		42/50 (84%)	35/50 (70%)						
<b>Overall Incidence</b>	Total	77/100 (77%)	Mean 77%	SD 9.9%					
.....									
<b>*Testes:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)						
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD 0%					
.....									
<b>*Thymus:</b>									
<b>Thymoma Benign</b>									
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)		
<b>Overall Incidence</b>	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thymus:</b>									
<b>Thymoma Malignant</b>									
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)		
<b>Overall Incidence</b>	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thymus:</b>									
<b>Thymoma NOS</b>									
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)		
<b>Overall Incidence</b>	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thymus:</b>									
<b>Thymoma: Benign, Malignant, NOS</b>									
		0/50 (0%)	0/44 (0%)			0/50 (0%)	0/48 (0%)		
<b>Overall Incidence</b>	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	

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

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

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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		Male				Female			
<b>*Thyroid Gland: C-Cell: Adenoma</b>									
		3/50 (6%)	6/46 (13%)		4/50 (8%)	4/42 (10%)			
<b>Overall Incidence</b>	Total	9/96 (9.38%)	Mean 9.52%	SD 4.98%	Total	8/92 (8.7%)	Mean 8.76%	SD 1.08%	
.....									
<b>*Thyroid Gland: C-Cell: Carcinoma</b>									
		1/50 (2%)	0/46 (0%)		0/50 (0%)	3/42 (7%)			
<b>Overall Incidence</b>	Total	1/96 (1.04%)	Mean 1%	SD 1.41%	Total	3/92 (3.26%)	Mean 3.57%	SD 5.05%	
.....									
<b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b>									
		4/50 (8%)	6/46 (13%)		4/50 (8%)	7/42 (17%)			
<b>Overall Incidence</b>	Total	10/96 (10.42%)	Mean 10.52%	SD 3.57%	Total	11/92 (11.96%)	Mean 12.33%	SD 6.13%	
.....									
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>									
		3/50 (6%)	0/46 (0%)		0/50 (0%)	0/42 (0%)			
<b>Overall Incidence</b>	Total	3/96 (3.12%)	Mean 3%	SD 4.24%	Total	0/92 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
		0/50 (0%)	0/46 (0%)		0/50 (0%)	0/42 (0%)			
<b>Overall Incidence</b>	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/92 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
		3/50 (6%)	0/46 (0%)		0/50 (0%)	0/42 (0%)			
<b>Overall Incidence</b>	Total	3/96 (3.12%)	Mean 3%	SD 4.24%	Total	0/92 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: May2011  
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 Species: RATS  
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		Male				Female			
<b>#Tissue NOS:</b>									
<b>Paranglioma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Tongue:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Tongue:</b>									
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(0%)	Mean 0% SD 0%
.....									
<b>#Tongue:</b>									
<b>Squamous Cell Papilloma</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	0/100	(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	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(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	0/100	(0%)	Mean 0%	SD 0%	Total	0/100	(0%)	Mean 0% SD 0%

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

Version: May2011  
 Contract/Lab: All Laboratories  
 Species: RATS  
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		Male				Female			
<b>*Urinary Bladder:</b>									
<b>  Carcinoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(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	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>*Urinary Bladder:</b>									
<b>  Hemangiosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>*Urinary Bladder:</b>									
<b>  Papilloma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
<b>#Uterus:</b>									
<b>  Adenoma</b>									
						0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>						0/100	(0%)	Mean 0%	SD 0%
.....									
<b>#Uterus:</b>									
<b>  Carcinoma</b>									
						0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>						0/100	(0%)	Mean 0%	SD 0%
.....									

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

#: Denominator is number of animals necropsied

Version: May2011  
 Contract/Lab: All Laboratories  
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	Male	Female
<b>#Uterus:</b> Deciduoma Benign		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
<b>#Uterus:</b> Leiomyosarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
<b>#Uterus:</b> Polyp Stromal		
Overall Incidence	Total 9/50 (18%) 26/100 (26%)	17/50 (34%) Mean 26% SD 11.31%
<b>#Uterus:</b> Sarcoma		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
<b>#Uterus:</b> Sarcoma Stromal		
Overall Incidence	Total 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
<b>#Uterus:</b> Sarcoma Stromal or Polyp Stromal		
Overall Incidence	Total 9/50 (18%) 26/100 (26%)	17/50 (34%) Mean 26% SD 11.31%

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

#: Denominator is number of animals necropsied



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		Male			Female		
<b>#Uterus:</b>							
<b>Schwannoma Malignant</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)	Mean	0%	SD	0%
.....							
<b>#Vagina:</b>							
<b>Polyp</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)	Mean	0%	SD	0%
.....							
<b>#Vagina:</b>							
<b>Sarcoma</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (0%)	Mean	0%	SD	0%
.....							
<b>#Vagina:</b>							
<b>Schwannoma Malignant</b>							
			0/50 (0%)		0/50 (0%)		
<b>Overall Incidence</b>		Total	0/100 (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%)
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD	0%	Total	0/100 (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%)
<b>Overall Incidence</b>	Total	0/100 (0%)	Mean 0%	SD	0%	Total	0/100 (0%)
						Mean	0%
						SD	0%
.....							

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

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

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

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Report Date: 05/18/2011

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

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