

Version: Jun2013
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: CORN OIL

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Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	059903103	03/23/05	727	50(3)	38(706)	512.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Battelle Columbus Laboratory	052010703	10/20/04	727	50(3)	37(702)	503.5	N,N-Dimethyl-p-toluidine
Female							
Battelle Columbus Laboratory	059903103	03/24/05	728	50(5)	37(700)	350.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Battelle Columbus Laboratory	052010703	10/21/04	728	50(5)	33(704)	354.1	N,N-Dimethyl-p-toluidine

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		Male			Female		
#All Organs:							
Benign Tumors							
		50/50 (100%)	49/49 (100%)	48/50 (96%)	47/50 (94%)	43/50 (86%)	46/50 (92%)
Overall Incidence	Total	147/149 (98.66%)	Mean 98.67%	SD 2.31%	Total 136/150 (90.67%)	Mean 90.67%	SD 4.16%
.....							
#All Organs:							
Malignant Tumors							
		13/50 (26%)	17/49 (35%)	20/50 (40%)	12/50 (24%)	11/50 (22%)	23/50 (46%)
Overall Incidence	Total	50/149 (33.56%)	Mean 33.56%	SD 7.07%	Total 46/150 (30.67%)	Mean 30.67%	SD 13.32%
.....							
#All Organs:							
Malignant and Benign Tumors							
		50/50 (100%)	49/49 (100%)	49/50 (98%)	49/50 (98%)	46/50 (92%)	49/50 (98%)
Overall Incidence	Total	148/149 (99.33%)	Mean 99.33%	SD 1.15%	Total 144/150 (96%)	Mean 96%	SD 3.46%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (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

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		Male			Female		
#All Organs:							
Histiocytic Sarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated							
		9/50 (18%)	7/49 (14%)	14/50 (28%)	8/50 (16%)	5/50 (10%)	15/50 (30%)
Overall Incidence	Total	30/149 (20.13%)	Mean 20.1%	SD 7.09%	Total	28/150 (18.67%)	Mean 18.67% SD 10.26%
.....							
#All Organs:							
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#All Organs:							
Mesothelioma: Benign, Malignant, NOS							
		3/50 (6%)	3/49 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/149 (4.7%)	Mean 4.71%	SD 2.35%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Mesothelioma: Malignant							
		3/50 (6%)	3/49 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/149 (4.7%)	Mean 4.71%	SD 2.35%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Osteoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

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		Male			Female		
#All Organs:							
Osteosarcoma							
		0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Osteosarcoma or Osteoma							
		0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Adrenal Cortex:							
Adenoma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2% SD 3.46%
.....							
*Adrenal Cortex:							
Carcinoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Adrenal Medulla:							
Pheochromocytoma Benign							
		11/50 (22%)	5/49 (10%)	6/50 (12%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	22/149 (14.77%)	Mean 14.73%	SD 6.36%	Total	7/150 (4.67%)	Mean 4.67% SD 1.15%
.....							
*Adrenal Medulla:							
Pheochromocytoma Complex							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%

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		Male			Female		
*Adrenal Medulla:							
Pheochromocytoma Malignant							
		2/50 (4%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Adrenal Medulla:							
Pheochromocytoma: Benign, Complex, Malignant, NOS							
		12/50 (24%)	5/49 (10%)	8/50 (16%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	25/149 (16.78%)	Mean 16.73%	SD 6.93%	Total	7/150 (4.67%)	Mean 4.67% SD 1.15%
.....							
#Blood Vessel:							
Leiomyosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Bone:							
Chordoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Bone:							
Osteoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Bone:							
Osteosarcoma							
		0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0% SD 0%

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		Male			Female		
#Bone:							
Osteosarcoma or Osteoma							
		0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Brain:							
Glioma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Brain:							
Glioma Benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Brain:							
Glioma Malignant							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Brain:							
Oligodendroglioma, Glioma, or Astrocytoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Brain:							
Osteosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

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		Male			Female		
*Clitoral/Preputial Gland: Adenoma							
		4/50 (8%)	0/49 (0%)	0/50 (0%)	5/50 (10%)	2/50 (4%)	5/50 (10%)
Overall Incidence	Total	4/149 (2.68%)	Mean 2.67%	SD 4.62%	Total	12/150 (8%)	Mean 8% SD 3.46%
.....							
*Clitoral/Preputial Gland: Carcinoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	2/150 (1.33%)	Mean 1.33% SD 2.31%
.....							
*Clitoral/Preputial Gland: Carcinoma or Adenoma							
		4/50 (8%)	1/49 (2%)	0/50 (0%)	5/50 (10%)	4/50 (8%)	5/50 (10%)
Overall Incidence	Total	5/149 (3.36%)	Mean 3.35%	SD 4.16%	Total	14/150 (9.33%)	Mean 9.33% SD 1.15%
.....							
*Clitoral/Preputial Gland: Sarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Ear: Neural Crest Tumor							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%
.....							
#Eye: Melanoma Benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%

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		Male			Female		
#Eye:							
Melanoma Malignant							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Harderian Gland:							
Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Harderian Gland:							
Carcinoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Harderian Gland:							
Carcinoma or Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Heart:							
Schwannoma Benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Heart:							
Schwannoma Malignant							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (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			
#Intestine Large: Colon/Rectum:									
Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Carcinoma or Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Leiomyoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Schwannoma Malignant									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Intestine Small: Ileum:									
Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male			Female		
#Intestine Small: Jejunum:							
Leiomyoma							
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Intestine Small: Jejunum:							
Leiomyosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%
							SD 1.15%
.....							
#Intestine Small: Site Unspecified:							
Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Intestine Small: Site Unspecified:							
Carcinoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Intestine Small: Site Unspecified:							
Carcinoma or Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
							SD 0%
.....							
#Intestine Small: Site Unspecified:							
Leiomyoma							
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (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
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		Male			Female			
#Intestine Small: Site Unspecified:								
Leiomyosarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Intestine Small: Site Unspecified:								
Schwannoma Malignant								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Islets, Pancreatic:								
Adenoma								
		4/50 (8%)	4/49 (8%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	10/149 (6.71%)	Mean 6.72%	SD 2.36%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
*Islets, Pancreatic:								
Carcinoma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Islets, Pancreatic:								
Carcinoma or Adenoma								
		4/50 (8%)	4/49 (8%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	11/149 (7.38%)	Mean 7.39%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
*Kidney: Pelvis and Transitional Epithelium:								
Papilloma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (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: Jun2013
 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		
*Kidney: Renal Tubule: Adenoma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Carcinoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Carcinoma or Adenoma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Lipoma							
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Sarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (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: Jun2013
 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: CORN OIL

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		Male			Female		
*Liver:							
Hepatocellular Adenoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Liver:							
Hepatocellular Carcinoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Liver:							
Hepatocellular Carcinoma or Hepatoblastoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Liver:							
Hepatocellular Carcinoma or Hepatocellular Adenoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Liver:							
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Liver:							
Ito Cell Tumor Benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (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: Jun2013
 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		
*Lung:							
Alveolar/Bronchiolar Adenoma							
		1/50 (2%)	2/49 (4%)	0/50 (0%)	4/50 (8%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2.03%	SD 2.04%	Total	5/150 (3.33%)	Mean 3.33% SD 4.16%
.....							
*Lung:							
Alveolar/Bronchiolar Carcinoma							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Lung:							
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma							
		1/50 (2%)	2/49 (4%)	0/50 (0%)	4/50 (8%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2.03%	SD 2.04%	Total	5/150 (3.33%)	Mean 3.33% SD 4.16%
.....							
*Lung:							
Fibrosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Mammary Gland:							
Adenolipoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Mammary Gland:							
Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33% SD 2.31%

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

Version: Jun2013
 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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		Male				Female			
#Mammary Gland:									
Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
#Mammary Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	
.....									
#Mammary Gland:									
Fibroadenoma									
		2/50 (4%)	0/49 (0%)	0/50 (0%)		23/50 (46%)	24/50 (48%)	29/50 (58%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	76/150 (50.67%)	Mean 50.67%	SD 6.43%	
.....									
#Mammary Gland:									
Fibroma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		2/50 (4%)	0/49 (0%)	0/50 (0%)		23/50 (46%)	25/50 (50%)	29/50 (58%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	77/150 (51.33%)	Mean 51.33%	SD 6.11%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		2/50 (4%)	0/49 (0%)	0/50 (0%)		23/50 (46%)	26/50 (52%)	30/50 (60%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	79/150 (52.67%)	Mean 52.67%	SD 7.02%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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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		Male				Female			
#Mesentery:									
Fibrous Histiocytoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Schwannoma Malignant									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Papilloma Squamous or Papilloma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	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: Jun2013
 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: CORN OIL

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		Male			Female			
#Oral Mucosa:								
Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Oral Mucosa:								
Squamous Cell Papilloma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Ovary:								
Cystadenoma								
					0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total				1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....								
*Ovary:								
Fibrosarcoma								
					0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total				1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....								
*Ovary:								
Granulosa Cell Tumor Benign								
					0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total				0/150 (0%)	Mean 0%	SD 0%	
.....								
*Ovary:								
Granulosa Cell Tumor Malignant								
					0/50 (0%)	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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
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				Male					Female
*Ovary:									
Granulosa Cell Tumor: 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%	
.....									
*Ovary:									
Granulosa-Theca Tumor Malignant									
				0/50 (0%)					0/50 (0%)
				0/50 (0%)					0/50 (0%)
Overall Incidence				Total	0/150 (0%)	Mean 0%		SD 0%	
.....									
*Ovary:									
Schwannoma Malignant									
				0/50 (0%)					0/50 (0%)
				0/50 (0%)					0/50 (0%)
Overall Incidence				Total	0/150 (0%)	Mean 0%		SD 0%	
.....									
*Ovary:									
Sertoli Cell Tumor Malignant									
				0/50 (0%)					0/50 (0%)
				0/50 (0%)					0/50 (0%)
Overall Incidence				Total	0/150 (0%)	Mean 0%		SD 0%	
.....									
*Ovary:									
Tubulostromal Adenoma									
				1/50 (2%)					0/50 (0%)
				1/50 (2%)					0/50 (0%)
Overall Incidence				Total	1/150 (0.67%)	Mean 0.67%		SD 1.15%	
.....									
*Pancreas:									
Adenoma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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

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		Male			Female			
*Pancreas:								
Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Pancreas:								
Mixed Tumor Benign								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Parathyroid Gland:								
Adenoma								
		0/47 (0%)	1/49 (2%)	0/49 (0%)	1/38 (3%)	0/44 (0%)	0/50 (0%)	
Overall Incidence	Total	1/145 (0.69%)	Mean 0.68%	SD 1.18%	Total	1/132 (0.76%)	Mean 0.88%	SD 1.52%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Adenoma								
		38/50 (76%)	21/49 (43%)	23/50 (46%)	34/50 (68%)	29/50 (58%)	31/50 (62%)	
Overall Incidence	Total	82/149 (55.03%)	Mean 54.95%	SD 18.3%	Total	94/150 (62.67%)	Mean 62.67%	SD 5.03%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma or Adenoma								
		38/50 (76%)	21/49 (43%)	24/50 (48%)	36/50 (72%)	30/50 (60%)	31/50 (62%)	
Overall Incidence	Total	83/149 (55.7%)	Mean 55.62%	SD 17.84%	Total	97/150 (64.67%)	Mean 64.67%	SD 6.43%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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			
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Ganglioneuroma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Pituitary Gland: Pars Intermedia:								
Adenoma								
		1/50 (2%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Pituitary Gland: Pars Intermedia:								
Carcinoma or Adenoma								
		1/50 (2%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Pituitary Gland: Pars Nervosa:								
Craniopharyngioma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Prostate:								
Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%				
.....								
*Prostate:								
Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%				

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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		Male				Female					
*Salivary Glands:											
 Carcinoma											
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Salivary Glands:											
 Carcinoma or Adenoma											
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Salivary Glands:											
 Sarcoma											
		0/50	(0%)	0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/149	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Salivary Glands:											
 Schwannoma Malignant											
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Seminal Vesicle:											
 Adenoma											
		0/50	(0%)	0/49	(0%)	0/50	(0%)				
Overall Incidence	Total	0/149	(0%)	Mean 0%	SD 0%						
.....											
#Skeletal Muscle:											
 Fibrous Histiocytoma											
		0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/149	(0.67%)	Mean 0.68%	SD 1.18%	Total	0/150	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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 Route: GAVAGE
 Vehicle: CORN OIL

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		Male			Female			
#Skeletal Muscle:								
Lipoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma								
		1/50 (2%)	2/49 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma or Basosquamous Tumor Benign								
		1/50 (2%)	2/49 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma								
		1/50 (2%)	2/49 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female			
#Skin:								
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma								
Overall Incidence	Total	1/50 (2%) 4/149 (2.68%)	2/49 (4%) Mean 2.69%	1/50 (2%) SD 1.2%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Skin:								
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma								
Overall Incidence	Total	2/50 (4%) 8/149 (5.37%)	2/49 (4%) Mean 5.36%	4/50 (8%) SD 2.29%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Skin:								
Fibroma								
Overall Incidence	Total	1/50 (2%) 14/149 (9.4%)	7/49 (14%) Mean 9.43%	6/50 (12%) SD 6.53%	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
Overall Incidence	Total	2/50 (4%) 15/149 (10.07%)	7/49 (14%) Mean 10.1%	6/50 (12%) SD 5.4%	Total	1/50 (2%) 6/150 (4%)	1/50 (2%) Mean 4%	4/50 (8%) SD 3.46%
#Skin:								
Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female			
#Skin:								
Fibrous Histiocytoma								
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangiosarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Keratoacanthoma								
		2/50 (4%)	0/49 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 3.06%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Lipoma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Liposarcoma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Neural Crest Tumor								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (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: Jun2013
 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		
#Skin:							
Neurofibroma or Schwannoma benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Neurofibrosarcoma or Schwannoma (malignant or NOS)							
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)							
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Sarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Schwannoma Benign							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Schwannoma Malignant							
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male				Female			
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		2/50 (4%)	0/49 (0%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 3.06%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		2/50 (4%)	0/49 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 3.06%	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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female		
#Skin:							
Trichoepithelioma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin: Sebaceous Gland:							
Adenoma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin: Sebaceous Gland:							
Carcinoma or Adenoma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Spinal Cord:							
Glioma Malignant							
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Carcinoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Carcinoma or Adenoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female			
#Stomach, Glandular:								
Sarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Testes:								
Adenoma								
		37/50 (74%)	37/49 (76%)	40/50 (80%)				
Overall Incidence	Total	114/149 (76.51%)	Mean 76.5%	SD 3.12%				
.....								
*Testes:								
Hemangioma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)				
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%				
.....								
*Thymus:								
Thymoma Benign								
		1/47 (2%)	0/48 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	1/145 (0.69%)	Mean 0.71%	SD 1.23%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
.....								
*Thymus:								
Thymoma Malignant								
		0/47 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%
.....								
*Thymus:								
Thymoma NOS								
		0/47 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female			
*Thymus:								
Thymoma: Benign, Malignant, NOS								
		1/47 (2%)	0/48 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	1/145 (0.69%)	Mean 0.71%	SD 1.23%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
.....								
*Thyroid Gland: C-Cell:								
Adenoma								
		10/50 (20%)	8/49 (16%)	11/50 (22%)	11/49 (22%)	5/50 (10%)	9/49 (18%)	
Overall Incidence	Total	29/149 (19.46%)	Mean 19.44%	SD 2.88%	Total	25/148 (16.89%)	Mean 16.94%	SD 6.35%
.....								
*Thyroid Gland: C-Cell:								
Carcinoma								
		1/50 (2%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/148 (0%)	Mean 0%	SD 0%
.....								
*Thyroid Gland: C-Cell:								
Carcinoma or Adenoma								
		11/50 (22%)	8/49 (16%)	11/50 (22%)	11/49 (22%)	5/50 (10%)	9/49 (18%)	
Overall Incidence	Total	30/149 (20.13%)	Mean 20.11%	SD 3.28%	Total	25/148 (16.89%)	Mean 16.94%	SD 6.35%
.....								
*Thyroid Gland: Follicular Cell:								
Adenoma								
		2/50 (4%)	1/49 (2%)	1/50 (2%)	1/49 (2%)	1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	4/149 (2.68%)	Mean 2.68%	SD 1.14%	Total	3/148 (2.03%)	Mean 2.03%	SD 0.02%
.....								
*Thyroid Gland: Follicular Cell:								
Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		2/50 (4%)	1/49 (2%)	1/50 (2%)	1/49 (2%)	1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	4/149 (2.68%)	Mean 2.68%	SD 1.14%	Total	3/148 (2.03%)	Mean 2.03%	SD 0.02%
.....								
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Tooth: Adamantinoma Malignant								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Urinary Bladder: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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		Male			Female		
*Urinary Bladder:							
 Carcinoma or Papilloma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
*Urinary Bladder:							
 Hemangiosarcoma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Urinary Bladder:							
 Papilloma							
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Uterus:							
 Adenoma							
					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Uterus:							
 Carcinoma							
					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Uterus:							
 Leiomyosarcoma							
					0/50 (0%)	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: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

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	Male	Female
#Uterus: Polyp Stromal		
	3/50 (6%)	7/50 (14%)
Overall Incidence	Total 13/150 (8.67%)	Mean 8.67% SD 4.62%
#Uterus: Sarcoma		
	0/50 (0%)	0/50 (0%)
Overall Incidence	Total 0/150 (0%)	Mean 0% SD 0%
#Uterus: Sarcoma Stromal		
	0/50 (0%)	1/50 (2%)
Overall Incidence	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
#Uterus: Sarcoma Stromal or Polyp Stromal		
	3/50 (6%)	7/50 (14%)
Overall Incidence	Total 13/150 (8.67%)	Mean 8.67% SD 4.62%
#Uterus: Schwannoma Malignant		
	1/50 (2%)	0/50 (0%)
Overall Incidence	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
#Vagina: Polyp		
	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: Jun2013
 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: CORN OIL

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 Report Date: 06/05/2013

Male					Female						
#Vagina:											
Sarcoma											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence					Total	0/150	(0%)	Mean 0%	SD 0%		
.....											
#Vagina:											
Schwannoma Malignant											
					0/50	(0%)	0/50	(0%)	1/50	(2%)	
Overall Incidence					Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%		
.....											
#Zymbal's Gland:											
Adenoma											
		0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence		Total	0/149	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%
.....											
#Zymbal's Gland:											
Carcinoma											
		1/50	(2%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence		Total	1/149	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%
.....											
#Zymbal's Gland:											
Carcinoma or Adenoma											
		1/50	(2%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence		Total	1/149	(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