

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: SKIN  
Vehicle: ETHANOL

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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>							
Battelle Columbus Laboratory	059902805	09/16/02	729	50(1)	21(676)	506.2	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/10/02	728	50(1)	25(680)	510.4	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
<b>Female</b>							
Battelle Columbus Laboratory	059902805	09/17/02	730	50(1)	19(646)	341.0	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/11/02	729	50(1)	29(695)	337.8	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

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		Male			Female		
<b>#All Organs:</b>							
<b>Benign Tumors</b>							
		49/50 (98%)	46/50 (92%)	46/50 (92%)	37/50 (74%)	46/50 (92%)	47/50 (94%)
		47/50 (94%)			43/50 (86%)		
<b>Overall Incidence</b>	Total	188/200 (94%)	Mean 94%	SD 2.83%	Total	173/200 (86.5%)	Mean 86.5% SD 9%
.....							
<b>#All Organs:</b>							
<b>Malignant Tumors</b>							
		26/50 (52%)	23/50 (46%)	33/50 (66%)	19/50 (38%)	15/50 (30%)	22/50 (44%)
		22/50 (44%)			12/50 (24%)		
<b>Overall Incidence</b>	Total	104/200 (52%)	Mean 52%	SD 9.93%	Total	68/200 (34%)	Mean 34% SD 8.79%
.....							
<b>#All Organs:</b>							
<b>Malignant and Benign Tumors</b>							
		49/50 (98%)	50/50 (100%)	48/50 (96%)	44/50 (88%)	48/50 (96%)	49/50 (98%)
		49/50 (98%)			45/50 (90%)		
<b>Overall Incidence</b>	Total	196/200 (98%)	Mean 98%	SD 1.63%	Total	186/200 (93%)	Mean 93% SD 4.76%
.....							
<b>#All Organs:</b>							
<b>Hemangioma</b>							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0% SD 0%
.....							
<b>#All Organs:</b>							
<b>Hemangiosarcoma</b>							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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>Hemangiosarcoma or Hemangioma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Histiocytic Sarcoma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#All Organs:</b>									
<b>Leukemia: Erythrocytic</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>									
		17/50 (34%)	17/50 (34%)	26/50 (52%)		12/50 (24%)	10/50 (20%)	18/50 (36%)	
		11/50 (22%)				8/50 (16%)			
<b>Overall Incidence</b>	Total	71/200 (35.5%)	Mean 35.5%	SD 12.37%	Total	48/200 (24%)	Mean 24%	SD 8.64%	
.....									
<b>#All Organs:</b>									
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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>Mesothelioma: Benign</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Benign, Malignant, NOS</b>									
		2/50 (4%)	1/50 (2%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	9/200 (4.5%)	Mean 4.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Mesothelioma: Malignant</b>									
		2/50 (4%)	0/50 (0%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Osteoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			1/50 (2%)				
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#All Organs:</b>									
<b>Osteosarcoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)				
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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>Osteosarcoma or Osteoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Adenoma</b>									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	4/50 (8%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Ganglioneuroma</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (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>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Benign</b>									
		3/50 (6%)	5/50 (10%)	11/49 (22%)		1/50 (2%)	1/50 (2%)	1/49 (2%)	
		4/50 (8%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	23/199 (11.56%)	Mean 11.61%	SD 7.41%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Complex</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
		3/50 (6%)	5/50 (10%)	11/49 (22%)		1/50 (2%)	1/50 (2%)	1/49 (2%)	
		5/50 (10%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	24/199 (12.06%)	Mean 12.11%	SD 7.14%	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	
.....									
<b>#Bone:</b>									
<b>Chordoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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>#Bone:</b>									
<b>Osteoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Bone:</b>									
<b>Osteosarcoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Bone:</b>									
<b>Osteosarcoma or Osteoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Brain:</b>									
<b>Astrocytoma Malignant</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Ependymoma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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>*Brain:</b>									
<b>Ependymoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Glioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Glioma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Glioma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Granular Cell Tumor Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied



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		Male				Female			
<b>*Brain:</b>									
<b>Oligodendroglioma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Brain:</b>									
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Brain:</b>									
<b>Osteosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Schwannoma Malignant</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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>*Clitoral/Preputial Gland:</b>									
<b>Adenoma</b>									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	6/50 (12%)	6/50 (12%)	
		0/50 (0%)				3/50 (6%)			
<b>Overall Incidence</b>	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	17/200 (8.5%)	Mean 8.5%	SD 4.12%	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	4/200 (2%)	Mean 2%	SD 2.83%	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		2/50 (4%)	2/50 (4%)	4/50 (8%)		2/50 (4%)	6/50 (12%)	9/50 (18%)	
		0/50 (0%)				4/50 (8%)			
<b>Overall Incidence</b>	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	21/200 (10.5%)	Mean 10.5%	SD 5.97%	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Ear:</b>									
<b>Neural Crest Tumor</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Esophagus:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Eye:</b>									
<b>Melanoma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Eye:</b>									
<b>Melanoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Eye:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Harderian Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Harderian Gland:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
<b>*Heart:</b>									
<b>Schwannoma Benign</b>									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Heart:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
<b>#Intestine Large: Colon/Rectum:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Jejunum:</b>									
<b>Granular Cell Tumor Malignant</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Intestine Small: Site Unspecified: Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Intestine Small: Site Unspecified: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified: Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified: Leiomyoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Intestine Small: Site Unspecified:</b>									
<b>Leiomyosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Intestine Small: Site Unspecified:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Adenoma</b>									
		3/50 (6%)	6/50 (12%)	5/49 (10%)		0/50 (0%)	0/50 (0%)	3/49 (6%)	
		3/50 (6%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	17/199 (8.54%)	Mean 8.55%	SD 3.04%	Total	5/199 (2.51%)	Mean 2.53%	SD 3.05%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	3/49 (6%)		1/50 (2%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	3/199 (1.51%)	Mean 1.53%	SD 3.06%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Islets, Pancreatic:</b>									
<b>Carcinoma or Adenoma</b>									
		3/50 (6%)	6/50 (12%)	8/49 (16%)		1/50 (2%)	0/50 (0%)	3/49 (6%)	
		3/50 (6%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	20/199 (10.05%)	Mean 10.08%	SD 5.03%	Total	6/199 (3.02%)	Mean 3.03%	SD 2.63%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Kidney: Pelvis and Transitional Epithelium: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Pelvis and Transitional Epithelium: Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Kidney: Renal Tubule: Carcinoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Lipoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Kidney: Renal Tubule: Mesenchymal Tumor Benign</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule: Mesenchymal Tumor Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Kidney: Renal Tubule:</b>									
<b>  Nephroblastoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>  Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Liver:</b>									
<b>  Cholangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>  Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>  Hepatocellular Adenoma</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 2%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
<b>*Liver:</b>									
<b>Ito Cell Tumor Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Adenoma</b>									
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	4/50 (8%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	8/200 (4%)	Mean 4%	SD 2.83%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Carcinoma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>									
		5/50 (10%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	4/50 (8%)	1/50 (2%)	
		4/50 (8%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	13/200 (6.5%)	Mean 6.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	
.....									
<b>*Lung:</b>									
<b>Fibrosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Lung:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Lung:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Lymph Node:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mammary Gland:</b>									
<b>Adenolipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mammary Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
<b>#Mammary Gland:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
		1/50 (2%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 1.15%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Mammary Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	3/50 (6%)	
		1/50 (2%)				3/50 (6%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	10/200 (5%)	Mean 5%	SD 2%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroadenoma</b>									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		16/50 (32%)	14/50 (28%)	19/50 (38%)	
		0/50 (0%)				24/50 (48%)			
<b>Overall Incidence</b>	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	73/200 (36.5%)	Mean 36.5%	SD 8.7%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma or Adenoma</b>									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		16/50 (32%)	15/50 (30%)	19/50 (38%)	
		0/50 (0%)				25/50 (50%)			
<b>Overall Incidence</b>	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	75/200 (37.5%)	Mean 37.5%	SD 9%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		17/50 (34%)	17/50 (34%)	21/50 (42%)	
		1/50 (2%)				26/50 (52%)			
<b>Overall Incidence</b>	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	81/200 (40.5%)	Mean 40.5%	SD 8.54%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Mesentery:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Mesentery:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				2/50 (4%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
<b>*Nose:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Nose:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Papilloma Squamous or Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Oral Mucosa:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: SKIN**  
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		Male				Female			
<b>#Oral Mucosa:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Ovary:</b>									
<b>Cystadenoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Ovary:</b>									
<b>Fibrosarcoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Ovary:</b>									
<b>Granulosa Cell Tumor Benign</b>									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
						1/50 (2%)			
<b>Overall Incidence</b>	Total				Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
<b>*Ovary:</b>									
<b>Granulosa Cell Tumor Malignant</b>									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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	Male			Female		
<b>*Ovary:</b>						
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>						
		1/50	(2%)	0/50	(0%)	1/50 (2%)
		1/50	(2%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)		Mean	1.5%	SD 1%
.....						
<b>*Ovary:</b>						
<b>Granulosa-Theca Tumor Benign</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)		Mean	0%	SD 0%
.....						
<b>*Ovary:</b>						
<b>Granulosa-Theca Tumor Malignant</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)		Mean	0%	SD 0%
.....						
<b>*Ovary:</b>						
<b>Schwannoma Malignant</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)		Mean	0%	SD 0%
.....						
<b>*Ovary:</b>						
<b>Tubulostromal Adenoma</b>						
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
<b>Overall Incidence</b>	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Pancreas:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Mixed Tumor Benign</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Mixed Tumor Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Parathyroid Gland:</b>									
<b>Adenoma</b>									
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/43 (0%)	0/46 (0%)	1/50 (2%)	
		0/50 (0%)				0/49 (0%)			
<b>Overall Incidence</b>	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/188 (0.53%)	Mean 0.5%	SD 1%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Adenoma</b>									
		35/49 (71%)	32/50 (64%)	33/50 (66%)		22/50 (44%)	35/50 (70%)	31/50 (62%)	
		33/50 (66%)				25/50 (50%)			
<b>Overall Incidence</b>	Total	133/199 (66.83%)	Mean 66.86%	SD 3.19%	Total	113/200 (56.5%)	Mean 56.5%	SD 11.7%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma</b>									
		0/49 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 2%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma or Adenoma</b>									
		35/49 (71%)	32/50 (64%)	35/50 (70%)		22/50 (44%)	35/50 (70%)	33/50 (66%)	
		33/50 (66%)				25/50 (50%)			
<b>Overall Incidence</b>	Total	135/199 (67.84%)	Mean 67.86%	SD 3.45%	Total	115/200 (57.5%)	Mean 57.5%	SD 12.48%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Ganglioneuroma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
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		Male				Female			
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>Adenoma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>Carcinoma or Adenoma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Pituitary Gland: Pars Nervosa:</b>									
<b>Craniopharyngioma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Prostate:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
<b>*Prostate:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
<b>Overall Incidence</b>	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Salivary Glands:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Salivary Glands:</b>									
<b>Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Seminal Vesicle:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
<b>Overall Incidence</b>	Total	0/200 (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>#Skeletal Muscle:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle:</b>									
<b>Hemangiosarcoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skeletal Muscle:</b>									
<b>Rhabdomyosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skeletal Muscle:</b>									
<b>Rhabdomyosarcoma or Rhabdomyoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Skin:</b>									
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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	Male				Female			
<b>#Skin:</b>								
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>								
		2/50 (4%)	2/50 (4%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/50 (6%)				1/50 (2%)		
<b>Overall Incidence</b>	Total	14/200 (7%)	Mean 7%	SD 4.76%	Total	2/200 (1%)	Mean 1%	SD 1.15%
.....								
<b>#Skin:</b>								
<b>Fibroma</b>								
		1/50 (2%)	7/50 (14%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		1/50 (2%)				1/50 (2%)		
<b>Overall Incidence</b>	Total	14/200 (7%)	Mean 7%	SD 6%	Total	6/200 (3%)	Mean 3%	SD 2.58%
.....								
<b>#Skin:</b>								
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		3/50 (6%)	8/50 (16%)	7/50 (14%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		1/50 (2%)				1/50 (2%)		
<b>Overall Incidence</b>	Total	19/200 (9.5%)	Mean 9.5%	SD 6.61%	Total	6/200 (3%)	Mean 3%	SD 2.58%
.....								
<b>#Skin:</b>								
<b>Fibrosarcoma</b>								
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
<b>Overall Incidence</b>	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
.....								
<b>#Skin:</b>								
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
<b>Overall Incidence</b>	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Skin:</b>									
<b>Fibrous Histiocytoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Keratoacanthoma</b>									
		0/50 (0%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	8/200 (4%)	Mean 4%	SD 3.27%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Lipoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: SKIN**  
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		Male				Female			
<b>#Skin:</b>									
<b>Liposarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Neural Crest Tumor</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Neurofibroma or Schwannoma benign</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

\*: 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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**Vehicle: ETHANOL**

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		Male				Female			
<b>#Skin:</b>									
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>									
		1/50 (2%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Schwannoma Benign</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Schwannoma Malignant</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma</b>									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

\*: 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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**Vehicle: ETHANOL**

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		Male				Female			
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma or Papilloma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>									
		1/50 (2%)	2/50 (4%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>									
		0/50 (0%)	2/50 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	10/200 (5%)	Mean 5%	SD 4.16%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Skin:</b>									
<b>Trichoepithelioma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin: Sebaceous Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin: Sebaceous Gland:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Spinal Cord:</b>									
<b>Astrocytoma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Spinal Cord:</b>									
<b>Astrocytoma Malignant</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Spinal Cord:</b>									
<b>    Glioma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Spleen:</b>									
<b>    Fibrosarcoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Spleen:</b>									
<b>    Fibrous Histiocytoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Spleen:</b>									
<b>    Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Spleen:</b>									
<b>    Leiomyosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Spleen:</b>									
<b>Sarcoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Leiomyosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Stomach, Glandular:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Glandular:</b>									
<b>Lipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Stomach, Glandular:</b>									
<b>Sarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Testes:</b>									
<b>Adenoma</b>									
		30/50 (60%)	37/50 (74%)	34/50 (68%)					
		37/50 (74%)							
<b>Overall Incidence</b>	Total	138/200 (69%)	Mean 69%	SD 6.63%					

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Testes:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		1/50 (2%)							
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
<b>*Thymus:</b>									
<b>Thymoma Benign</b>									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	1/50 (2%)	
		0/47 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%	
.....									
<b>*Thymus:</b>									
<b>Thymoma Malignant</b>									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)	
		0/47 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thymus:</b>									
<b>Thymoma NOS</b>									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)	
		0/47 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%	
.....									
<b>*Thymus:</b>									
<b>Thymoma: Benign, Malignant, NOS</b>									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	1/50 (2%)	
		0/47 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	0/195 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 1.15%	

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male			Female		
<b>*Thyroid Gland: C-Cell: Adenoma</b>							
		10/50 (20%)	10/50 (20%)	6/46 (13%)	6/50 (12%)	8/50 (16%)	7/50 (14%)
		9/50 (18%)			7/50 (14%)		
<b>Overall Incidence</b>	Total	35/196 (17.86%)	Mean 17.76%	SD 3.28%	Total	28/200 (14%)	Mean 14% SD 1.63%
.....							
<b>*Thyroid Gland: C-Cell: Carcinoma</b>							
		1/50 (2%)	2/50 (4%)	0/46 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	3/196 (1.53%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5% SD 1%
.....							
<b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b>							
		11/50 (22%)	12/50 (24%)	6/46 (13%)	6/50 (12%)	8/50 (16%)	8/50 (16%)
		9/50 (18%)			7/50 (14%)		
<b>Overall Incidence</b>	Total	38/196 (19.39%)	Mean 19.26%	SD 4.84%	Total	29/200 (14.5%)	Mean 14.5% SD 1.91%
.....							
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>							
		0/50 (0%)	0/50 (0%)	0/46 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)			1/50 (2%)		
<b>Overall Incidence</b>	Total	0/196 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5% SD 1%
.....							
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>							
		0/50 (0%)	1/50 (2%)	2/46 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
<b>Overall Incidence</b>	Total	3/196 (1.53%)	Mean 1.59%	SD 2.07%	Total	1/200 (0.5%)	Mean 0.5% SD 1%

\*: 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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Thyroid Gland: Follicular Cell:</b>									
<b>  Carcinoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	2/46 (4%)		2/50 (4%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				1/50 (2%)			
<b>Overall Incidence</b>	Total	3/196 (1.53%)	Mean 1.59%	SD 2.07%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
<b>#Tissue NOS:</b>									
<b>  Paraganglioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tongue:</b>									
<b>  Squamous Cell Carcinoma or Papilloma Squamous</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tongue:</b>									
<b>  Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>#Tooth:</b>									
<b>Adamantinoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tooth:</b>									
<b>Odontoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
<b>*Urinary Bladder:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>*Urinary Bladder:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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		Male				Female			
<b>*Urinary Bladder:</b>									
<b>Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
<b>Overall Incidence</b>	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Uterus:</b>									
<b>Adenoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Uterus:</b>									
<b>Carcinoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Uterus:</b>									
<b>Deciduoma Benign</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
<b>#Uterus:</b>									
<b>Leiomyosarcoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
<b>Overall Incidence</b>	Total				Total	0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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	Male	Female
<b>#Uterus:</b> <b>Polyp Stromal</b>		
	5/50 (10%) 7/50 (14%)	2/50 (4%) 10/50 (20%)
<b>Overall Incidence</b>	Total 24/200 (12%)	Mean 12% SD 6.73%
<b>#Uterus:</b> <b>Sarcoma</b>		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
<b>Overall Incidence</b>	Total 1/200 (0.5%)	Mean 0.5% SD 1%
<b>#Uterus:</b> <b>Sarcoma Stromal</b>		
	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
<b>Overall Incidence</b>	Total 2/200 (1%)	Mean 1% SD 1.15%
<b>#Uterus:</b> <b>Sarcoma Stromal or Polyp Stromal</b>		
	6/50 (12%) 7/50 (14%)	3/50 (6%) 10/50 (20%)
<b>Overall Incidence</b>	Total 26/200 (13%)	Mean 13% SD 5.77%
<b>#Uterus:</b> <b>Schwannoma Malignant</b>		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
<b>Overall Incidence</b>	Total 0/200 (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: SKIN**  
**Vehicle: ETHANOL**

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					Male		Female				
<b>#Vagina:</b>											
<b>Polyp</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
<b>Overall Incidence</b>					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
<b>#Vagina:</b>											
<b>Sarcoma</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
<b>Overall Incidence</b>					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
<b>#Vagina:</b>											
<b>Schwannoma Malignant</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)					
<b>Overall Incidence</b>					Total	0/200	(0%)	Mean	0%	SD	0%
.....											
<b>#Zymbal's Gland:</b>											
<b>Adenoma</b>											
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)
		0/50	(0%)					0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/200 (0.5%)		Mean	0.5%	SD	1%	Total	0/200	(0%)	Mean 0% SD 0%
.....											
<b>#Zymbal's Gland:</b>											
<b>Carcinoma</b>											
		0/50	(0%)	0/50	(0%)	1/50	(2%)			0/50	(0%)
		1/50	(2%)					0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	2/200 (1%)		Mean	1%	SD	1.15%	Total	0/200	(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: SKIN  
 Vehicle: ETHANOL

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 Report Date: 05/18/2011

		Male				Female								
<b>#Zymbal's Gland:</b>														
<b>Carcinoma or Adenoma</b>														
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)			
		1/50	(2%)					0/50	(0%)					
<b>Overall Incidence</b>	Total	3/200 (1.5%)		Mean	1.5%	SD	1%	Total	0/200 (0%)		Mean	0%	SD	0%

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

#: Denominator is number of animals necropsied