

Version: Mar2010
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

Page: 322
Report Date: 03/20/2010

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	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
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
Female							
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
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 323
 Report Date: 03/20/2010

		Male			Female		
#All Organs:							
Benign Tumors							
		49/50 (98%)	46/50 (92%)	47/50 (94%)	37/50 (74%)	46/50 (92%)	43/50 (86%)
Overall Incidence	Total	142/150 (94.67%)	Mean 94.67%	SD 3.06%	Total 126/150 (84%)	Mean 84%	SD 9.17%
.....							
#All Organs:							
Malignant Tumors							
		26/50 (52%)	23/50 (46%)	22/50 (44%)	19/50 (38%)	15/50 (30%)	12/50 (24%)
Overall Incidence	Total	71/150 (47.33%)	Mean 47.33%	SD 4.16%	Total 46/150 (30.67%)	Mean 30.67%	SD 7.02%
.....							
#All Organs:							
Malignant and Benign Tumors							
		49/50 (98%)	50/50 (100%)	49/50 (98%)	44/50 (88%)	48/50 (96%)	45/50 (90%)
Overall Incidence	Total	148/150 (98.67%)	Mean 98.67%	SD 1.15%	Total 137/150 (91.33%)	Mean 91.33%	SD 4.16%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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 Species: RATS
 Strain: F 344/N
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 324
 Report Date: 03/20/2010

		Male			Female			
#All Organs:								
Histiocytic Sarcoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#All Organs:								
Leukemia: Erythrocytic								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated								
		17/50 (34%)	17/50 (34%)	11/50 (22%)	12/50 (24%)	10/50 (20%)	8/50 (16%)	
Overall Incidence	Total	45/150 (30%)	Mean 30%	SD 6.93%	Total	30/150 (20%)	Mean 20%	SD 4%
.....								
#All Organs:								
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Mesothelioma: Benign								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Mesothelioma: Benign, Malignant, NOS								
		2/50 (4%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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Version: Mar2010
 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

Page: 325
 Report Date: 03/20/2010

		Male			Female			
#All Organs:								
Mesothelioma: Malignant								
		2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#All Organs:								
Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#All Organs:								
Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Adrenal Cortex:								
Adenoma								
		0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Adrenal Cortex:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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Version: Mar2010
 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

Page: 326
 Report Date: 03/20/2010

		Male				Female			
*Adrenal Medulla: Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma Benign									
		3/50 (6%)	5/50 (10%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma Complex									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma Malignant									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS									
		3/50 (6%)	5/50 (10%)	5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 2.31%	Total	3/150 (2%)	Mean 2%	SD 0%	

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Version: Mar2010
 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

Page: 327
 Report Date: 03/20/2010

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

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#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 328
 Report Date: 03/20/2010

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

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Version: Mar2010
 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

Page: 329
 Report Date: 03/20/2010

		Male				Female					
*Brain:											
Oligodendroglioma Benign											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Oligodendroglioma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Brain:											
Oligodendroglioma, Glioma, or Astrocytoma											
		0/50	(0%)	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%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Brain:											
Osteosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Schwannoma Malignant											
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Clitoral/Preputial Gland:											
Adenoma											
		2/50	(4%)	2/50	(4%)	0/50	(0%)	2/50	(4%)	6/50	(12%)
Overall Incidence	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	Total	11/150	(7.33%)	Mean 7.33%	SD 4.16%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 330
 Report Date: 03/20/2010

		Male			Female			
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%	Total	2/50 (4%) 12/150 (8%)	6/50 (12%) Mean 8%	4/50 (8%) SD 4%
*Clitoral/Preputial Gland: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Ear: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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Version: Mar2010
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 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

Page: 331
 Report Date: 03/20/2010

		Male				Female							
#Esophagus:													
Lipoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%			
.....													
#Eye:													
Melanoma Malignant													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
#Eye:													
Schwannoma Malignant													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
#Harderian Gland:													
Carcinoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
#Harderian Gland:													
Carcinoma or Adenoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%			
.....													
*Heart:													
Schwannoma Benign													
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/150	(1.33%)	Mean 1.33%	SD 2.31%	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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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 332
 Report Date: 03/20/2010

		Male			Female			
*Heart:								
Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Large: Colon/Rectum:								
Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
#Intestine Large: Colon/Rectum:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Large: Colon/Rectum:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
.....								
#Intestine Large: Colon/Rectum:								
Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Small: Duodenum:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 333
 Report Date: 03/20/2010

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

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

Version: Mar2010
 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

Page: 334
 Report Date: 03/20/2010

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

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 335
 Report Date: 03/20/2010

		Male				Female			
*Islets, Pancreatic:									
Adenoma									
		3/50 (6%)	6/50 (12%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 3.46%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		3/50 (6%)	6/50 (12%)	3/50 (6%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 3.46%	Total	3/150 (2%)	Mean 2%	SD 2%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

Version: Mar2010
 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

Page: 336
 Report Date: 03/20/2010

		Male			Female			
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

Version: Mar2010
 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

Page: 337
 Report Date: 03/20/2010

		Male				Female					
*Kidney: Renal Tubule:											
Mesenchymal Tumor Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule:											
Nephroblastoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Kidney: Renal Tubule:											
Sarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Liver:											
Cholangioma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Hemangiosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Liver:											
Hepatocellular Adenoma											
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	Total	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: Mar2010
 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

Page: 338
 Report Date: 03/20/2010

		Male				Female			
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
*Liver:									
Ito Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		4/50 (8%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)	
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 339
 Report Date: 03/20/2010

		Male			Female			
*Lung:								
Alveolar/Bronchiolar Carcinoma								
		1/50 (2%)	1/50 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
*Lung:								
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
		5/50 (10%)	2/50 (4%)	4/50 (8%)	0/50 (0%)	4/50 (8%)	0/50 (0%)	
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 3.06%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%
.....								
*Lung:								
Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Lung:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Lung:								
Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Lymph Node:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 340
 Report Date: 03/20/2010

		Male			Female			
#Mammary Gland:								
Adenolipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland:								
Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%
#Mammary Gland:								
Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	1/50 (2%) SD 1.15%
#Mammary Gland:								
Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	3/50 (6%) SD 2.31%
#Mammary Gland:								
Fibroadenoma								
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	16/50 (32%) 54/150 (36%)	14/50 (28%) Mean 36%	24/50 (48%) SD 10.58%
#Mammary Gland:								
Fibroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 341
 Report Date: 03/20/2010

		Male			Female		
#Mammary Gland:							
Fibroma, Fibroadenoma or Adenoma							
		3/50 (6%)	1/50 (2%)	0/50 (0%)	16/50 (32%)	15/50 (30%)	25/50 (50%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	56/150 (37.33%)	Mean 37.33% SD 11.02%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
		3/50 (6%)	1/50 (2%)	1/50 (2%)	17/50 (34%)	17/50 (34%)	26/50 (52%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	60/150 (40%)	Mean 40% SD 10.39%
.....							
#Mesentery:							
Fibrous Histiocytoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Lipoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Schwannoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/150 (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: Mar2010
 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

Page: 342
 Report Date: 03/20/2010

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

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

Version: Mar2010
 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

Page: 343
 Report Date: 03/20/2010

		Male				Female					
#Oral Mucosa:											
Squamous Cell Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Oral Mucosa:											
Squamous Cell Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Ovary:											
Cystadenoma											
						0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Ovary:											
Granulosa Cell Tumor Benign											
						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 Malignant											
						1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Ovary:											
Granulosa Cell Tumor: Benign, Malignant, NOS											
						1/50	(2%)	0/50	(0%)	1/50	(2%)
Overall Incidence						Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 344
 Report Date: 03/20/2010

					Male						Female			
*Ovary:														
Granulosa-Theca Tumor Benign														
					0/50	(0%)						0/50	(0%)	
Overall Incidence					Total	0/150	(0%)	Mean	0%	SD	0%	0/50	(0%)	
.....														
*Ovary:														
Granulosa-Theca Tumor Malignant														
					0/50	(0%)						0/50	(0%)	
Overall Incidence					Total	0/150	(0%)	Mean	0%	SD	0%	0/50	(0%)	
.....														
*Ovary:														
Tubulostromal Adenoma														
					0/50	(0%)						0/50	(0%)	
Overall Incidence					Total	0/150	(0%)	Mean	0%	SD	0%	0/50	(0%)	
.....														
*Pancreas:														
Adenoma														
			0/50	(0%)				0/50	(0%)				0/50	(0%)
Overall Incidence			Total	0/150	(0%)	Mean	0%	SD	0%				0/50	(0%)
.....														
*Pancreas:														
Carcinoma														
			0/50	(0%)				0/50	(0%)				0/50	(0%)
Overall Incidence			Total	0/150	(0%)	Mean	0%	SD	0%				0/50	(0%)
.....														
*Pancreas:														
Carcinoma or Adenoma														
			0/50	(0%)				0/50	(0%)				0/50	(0%)
Overall Incidence			Total	0/150	(0%)	Mean	0%	SD	0%				0/50	(0%)

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

Version: Mar2010
 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

Page: 345
 Report Date: 03/20/2010

		Male				Female			
*Pancreas:									
Mixed Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Parathyroid Gland:									
Adenoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/43 (0%)	0/46 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/138 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		35/49 (71%)	32/50 (64%)	33/50 (66%)		22/50 (44%)	35/50 (70%)	25/50 (50%)	25/50 (50%)
Overall Incidence	Total	100/149 (67.11%)	Mean 67.14%	SD 3.84%	Total	82/150 (54.67%)	Mean 54.67%	SD 13.61%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/49 (0%)	0/50 (0%)	0/50 (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 Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		35/49 (71%)	32/50 (64%)	33/50 (66%)		22/50 (44%)	35/50 (70%)	25/50 (50%)	25/50 (50%)
Overall Incidence	Total	100/149 (67.11%)	Mean 67.14%	SD 3.84%	Total	82/150 (54.67%)	Mean 54.67%	SD 13.61%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 346
 Report Date: 03/20/2010

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
 Ganglioneuroma									
		0/49 (0%)	0/50 (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									
		0/49 (0%)	0/50 (0%)	1/50 (2%)		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									
		0/49 (0%)	0/50 (0%)	1/50 (2%)		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									
		0/49 (0%)	0/50 (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%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%					
.....									
*Prostate:									
 Carcinoma or Adenoma									
		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: Mar2010
 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

Page: 347
 Report Date: 03/20/2010

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

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 348
 Report Date: 03/20/2010

		Male			Female			
#Skeletal Muscle:								
Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skeletal Muscle:								
Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skeletal Muscle:								
Rhabdomyosarcoma or Rhabdomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma or Basosquamous Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 349
 Report Date: 03/20/2010

		Male			Female		
#Skin:							
Basal Cell Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma							
		2/50 (4%)	2/50 (4%)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%
.....							
#Skin:							
Fibroma							
		1/50 (2%)	7/50 (14%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 6.93%	Total	3/150 (2%)	Mean 2% SD 2%
.....							
#Skin:							
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma							
		3/50 (6%)	8/50 (16%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 7.21%	Total	3/150 (2%)	Mean 2% SD 2%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 350
 Report Date: 03/20/2010

		Male			Female			
#Skin:								
Fibrosarcoma								
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Fibrous Histiocytoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Keratoacanthoma								
		0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 351
 Report Date: 03/20/2010

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

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 352
 Report Date: 03/20/2010

		Male			Female			
#Skin:								
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)								
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Schwannoma Benign								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Schwannoma Malignant								
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Squamous Cell Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

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

Version: Mar2010
 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

Page: 353
 Report Date: 03/20/2010

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

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

Version: Mar2010
 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

Page: 354
 Report Date: 03/20/2010

		Male			Female			
#Skin: Sebaceous Gland:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Spinal Cord:								
Astrocytoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Spinal Cord:								
Astrocytoma Malignant								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Spinal Cord:								
Glioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Spleen:								
Fibrosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Spleen:								
Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

Version: Mar2010
 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

Page: 355
 Report Date: 03/20/2010

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

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

Version: Mar2010
 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

Page: 356
 Report Date: 03/20/2010

		Male			Female			
#Stomach, Forestomach:								
Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Stomach, Glandular:								
Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Testes:								
Adenoma								
		30/50 (60%)	37/50 (74%)	37/50 (74%)				
Overall Incidence	Total	104/150 (69.33%)	Mean 69.33%	SD 8.08%				

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

Version: Mar2010
 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

Page: 357
 Report Date: 03/20/2010

		Male			Female		
*Testes:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
.....							
*Thymus:							
Thymoma Benign							
		0/49 (0%)	0/49 (0%)	0/47 (0%)	0/49 (0%)	0/45 (0%)	1/50 (2%)
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.67% SD 1.15%
.....							
*Thymus:							
Thymoma Malignant							
		0/49 (0%)	0/49 (0%)	0/47 (0%)	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0% SD 0%
.....							
*Thymus:							
Thymoma NOS							
		0/49 (0%)	0/49 (0%)	0/47 (0%)	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0% SD 0%
.....							
*Thymus:							
Thymoma: Benign, Malignant, NOS							
		0/49 (0%)	0/49 (0%)	0/47 (0%)	0/49 (0%)	0/45 (0%)	1/50 (2%)
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.67% SD 1.15%
.....							
*Thyroid Gland: C-Cell:							
Adenoma							
		10/50 (20%)	10/50 (20%)	9/50 (18%)	6/50 (12%)	8/50 (16%)	7/50 (14%)
Overall Incidence	Total	29/150 (19.33%)	Mean 19.33%	SD 1.15%	Total	21/150 (14%)	Mean 14% SD 2%

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

Version: Mar2010
 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

Page: 358
 Report Date: 03/20/2010

		Male			Female		
*Thyroid Gland: C-Cell: Carcinoma							
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
		11/50 (22%)	12/50 (24%)	9/50 (18%)	6/50 (12%)	8/50 (16%)	7/50 (14%)
Overall Incidence	Total	32/150 (21.33%)	Mean 21.33%	SD 3.06%	Total	21/150 (14%)	Mean 14% SD 2%
.....							
*Thyroid Gland: Follicular Cell: Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%
.....							
*Thyroid Gland: Follicular Cell: Carcinoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2% SD 2%
.....							
#Tissue NOS: Lipoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 359
 Report Date: 03/20/2010

		Male			Female		
#Tissue NOS:							
Paraganglioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Tongue:							
Squamous Cell Carcinoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Tongue:							
Squamous Cell Carcinoma or Papilloma Squamous							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Tongue:							
Squamous Cell Papilloma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Tooth:							
Adamantinoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Tooth:							
Odontoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%

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

Version: Mar2010
 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

Page: 360
 Report Date: 03/20/2010

		Male			Female			
*Urinary Bladder:								
 Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Urinary Bladder:								
 Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Urinary Bladder:								
 Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Urinary Bladder:								
 Papilloma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#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%

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

Version: Mar2010
 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

Page: 361
 Report Date: 03/20/2010

	Male		Female	
#Uterus:				
Deciduoma Benign				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
.....				
#Uterus:				
Hemangioma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
.....				
#Uterus:				
Hemangiosarcoma				
		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%
.....				
#Uterus:				
Polyp Stromal				
		5/50 (10%)	2/50 (4%)	7/50 (14%)
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 5.03%
.....				
#Uterus:				
Sarcoma				
		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	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: Mar2010
 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

Page: 362
 Report Date: 03/20/2010

		Male			Female		
#Uterus:							
Sarcoma Stromal							
			1/50 (2%)		1/50 (2%)	0/50 (0%)	
Overall Incidence		Total	2/150 (1.33%)		Mean 1.33%	SD 1.15%	
.....							
#Uterus:							
Sarcoma Stromal or Polyp Stromal							
			6/50 (12%)		3/50 (6%)	7/50 (14%)	
Overall Incidence		Total	16/150 (10.67%)		Mean 10.67%	SD 4.16%	
.....							
#Uterus:							
Schwannoma Malignant							
			0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/150 (0%)		Mean 0%	SD 0%	
.....							
#Vagina:							
Polyp							
			0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/150 (0%)		Mean 0%	SD 0%	
.....							
#Vagina:							
Sarcoma							
			0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/150 (0%)		Mean 0%	SD 0%	
.....							
#Zymbal's Gland:							
Adenoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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

Page: 363
 Report Date: 03/20/2010

		Male				Female							
#Zymbal's Gland:													
Carcinoma													
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/150 (0.67%)		Mean 0.67%		SD 1.15%		Total 0/150 (0%)		Mean 0%		SD 0%	
.....													
#Zymbal's Gland:													
Carcinoma or Adenoma													
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/150 (1.33%)		Mean 1.33%		SD 1.15%		Total 0/150 (0%)		Mean 0%		SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied