**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 180

Report Date: 05/18/2011

Species: RATS Strain: F 344/N Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

# **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		
Southern Research Institute	059902703	08/12/02	729	50(3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50(3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50(3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	729	50(3)	36(704)	452.1	Milk thistle extract
					Female		
Southern Research Institute	059902703	08/12/02	733	50(5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0(0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50(5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	732	50(5)	38(693)	328.4	Milk thistle extract

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
<b>3</b>		49/50 (98%) 50/50 (100%)	50/50 (100%)	47/50 (94%)		45/50 (90%) 39/50 (78%)		46/50 (92%)
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	130/150 (86.67%)	Mean 86.67%	SD 7.57%
#All Organs: Malignant Tumors								
		27/50 (54%) 26/50 (52%)	23/50 (46%)	29/50 (58%)		15/50 (30%) 18/50 (36%)		19/50 (38%)
Overall Incidence	Total	105/200 (52.5%)	Mean 52.5%	SD 5%	Total	52/150 (34.67%)	Mean 34.67%	SD 4.16%
#All Organs: Malignant and Benign T								
		50/50 (100%) 50/50 (100%)	50/50 (100%)	50/50 (100%)		47/50 (94%) 46/50 (92%)		48/50 (96%)
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	141/150 (94%)	Mean 94%	SD 2%
#All Organs: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/150 (0%) Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total Mean 0% SD 0% #All Organs: **Histiocytic Sarcoma** (2%) 0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)3/50 (6%)0/50 (0%)Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 3% Total 2/150 (1.33%) Mean 1.33% SD 1.15% **#All Organs:** Leukemia: Erythrocytic 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#All Organs:** Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 19/50 (38%)15/50 (30%)21/50 (42%)9/50 (18%)9/50 (18%)17/50 (34%)6/50 (12%)**Overall Incidence** Total 72/200 (36%) Mean 36% SD 5.16% Total 24/150 (16%) Mean 16% SD 3.46% **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Mesothelioma: 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 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Benign, Malignant, NOS 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant 1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 0% SD 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female
#All Organs: Osteosarcoma or Osteoma							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5% SD	1.91%	Total 0/	/150 (0%)	Mean 0% SD 0%
*Adrenal Cortex: Adenoma							
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		2/50 (4%) 0/48 (0%)	1/50 (2%)
Overall Incidence	Total	2/200 (1%)		SD 2%	Total 3/1	48 (2.03%) N	Mean 2% SD 2%
*Adrenal Cortex: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% S	SD 0%	Total 0/	/148 (0%) N	Mean 0% SD 0%
*Adrenal Medulla: Ganglioneuroma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% S	SD 0%	Total 0/	(146 (0%)	Mean 0% SD 0%
*Adrenal Medulla: Hemangioma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% S	SD 0%	Total 0/	/146 (0%) N	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	enign							
		8/50 (16%) 5/50 (10%)	8/50 (16%)	5/49 (10%)		1/50 (2%) 1/48 (2%)		0/48 (0%)
Overall Incidence	Total	26/199 (13.07%)	Mean 13.05%	SD 3.41%	Total	2/146 (1.37%)	Mean 1.36%	SD 1.18%
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/48 (2%)		0/48 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/146 (0.68%)	Mean 0.69%	SD 1.2%
*Adrenal Medulla: Pheochromocytoma Ma								
		3/50 (6%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		2/50 (4%) 0/48 (0%)		0/48 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/146 (1.37%)	Mean 1.33%	SD 2.31%
*Adrenal Medulla: Pheochromocytoma: B	enign, Comple	x, Malignant, NOS						
		11/50 (22%) 6/50 (12%)	8/50 (16%)	6/49 (12%)		3/50 (6%) 2/48 (4%)		0/48 (0%)
Overall Incidence	Total	31/199 (15.58%)	Mean 15.56%	SD 4.67%	Total	5/146 (3.42%)	Mean 3.39%	SD 3.07%
#Bone: Chordoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Bone: Osteoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma	ı							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Brain: Ependymoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (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%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

#### **Toxicology Data Management System**

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** \*Brain: Oligodendroglioma Benign 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/199 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Brain: Oligodendroglioma Malignant 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Mean 0% **Overall Incidence** Total 0/199 (0%) SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% ...... \*Brain: Oligodendroglioma, Glioma, or Astrocytoma 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% \*Brain: Osteosarcoma 0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Brain: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

.....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		1/50 (2%) 1/50 (2%)	5/50 (10%)	0/50 (0%)		10/50 (20%) 11/50 (22%)		5/50 (10%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 4.43%	Total	26/150 (17.33%)	Mean 17.33%	SD 6.43%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 3/50 (6%)		4/50 (8%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%) 3/50 (6%)	5/50 (10%)	2/50 (4%)		10/50 (20%) 14/50 (28%)		9/50 (18%)
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	Total	33/150 (22%)	Mean 22%	SD 5.29%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Melanoma 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Melanoma 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Schwannoma 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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
'Heart: Schwannoma 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rect Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Hemangioma (0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Carcinoma 1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Small: Duodenum: Schwannoma 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 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: **Granular Cell Tumor Malignant** 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (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%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 194

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Granular Cell Tumor Malignant** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% 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%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

.....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 195

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Site Unspection	cified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspec Schwannoma 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		1/50 (2%) 3/50 (6%)	1/49 (2%)	7/50 (14%)		2/49 (4%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.01%	SD 5.65%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%
slets, Pancreatic: Carcinoma								
		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/146 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%) 4/50 (8%)	2/49 (4%)	7/50 (14%)		2/49 (4%) 0/48 (0%)		0/49 (0%)
Overall Incidence	Total	15/199 (7.54%)	Mean 7.52%	SD 4.71%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 196

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male			Female	
*Kidney: Pelvis and Transiti Carcinoma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Pelvis and Transiti Carcinoma or Adenoma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Pelvis and Transiti Papilloma	onal Epitheliu	ım:					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Renal Tubule: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	
*Kidney: Renal Tubule: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%) 0/48 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%) Mean 0% SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page**: 197

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
*Kidney: Renal Tubule: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Lipoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Kidney: Renal Tubule: Nephroblastoma				
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/47 (0%) 1/49 (2%) 0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 1/144 (0.69%) Mean 0.68% SD 1.18%
*Liver: Cholangioma				
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 1.15%	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%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Adenoma				
		1/50 (2%) 3/50 (6%)	0/50 (0%) 1/50 (2%)	) 2/50 (4%) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5% SD 2.52%	Total 4/150 (2.67%) Mean 2.67% SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 199

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Liver: **Hepatocellular Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Liver: Hepatocellular Carcinoma or Hepatoblastoma (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% ...... \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma (2%)0/50 1/50 2/50 (4%)0/50 (0%)3/50 (6%)2/50 (4%)**Overall Incidence** Total 5/200 (2.5%) Mean 2.5% SD 2.52% Total 4/150 (2.67%) Mean 2.67% SD 2.31% \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)3/50 (6%)2/50 (4%)**Overall Incidence** Total 5/200 (2.5%) Mean 2.5% SD 2.52% Total 4/150 (2.67%) Mean 2.67% 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%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 200

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar A	Adenoma							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alv Total	veolar/Bronchiolar Adeno 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 1.5%	1/50 (2%) SD 1%	Total	1/50 (2%) 1/50 (2%) 3/150 (2%)	Mean 2%	1/50 (2%) SD 0%
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (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%)	0/30 (0%)	0/30 (0%)		0/50 (0%)		0/30 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 201

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Lung: **Squamous Cell Carcinoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% 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%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Mammary Gland:** Adenolipoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma 0/50 2/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)(4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 3/150 (2%) Mean 2% SD 2% #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)0/50 (0%)4/50 (8%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 8/150 (5.33%) Mean 5.33% SD 4.62%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 202

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)6/50 (12%) 0/50 (0%)(8%)11/150 (7.33%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 7.33% SD 5.03% #Mammary Gland: Fibroadenoma 2/50 (4%)0/50 (0%)1/50 (2%)29/50 (58%)(60%)0/50 (0%)28/50 (56%)Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total 87/150 (58%) Mean 58% SD 2% ...... **#Mammary Gland: Fibroma** 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% Mean 0% **#Mammary Gland:** Fibroma, Fibroadenoma or Adenoma 2/50 (4%)1/50 (2%)30/50 (60%)30/50 (60%)1/50 (2%)0/50 (0%)28/50 (56%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 1.63% Total 88/150 (58.67%) Mean 58.67% SD 2.31% #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma (4%)1/50 (2%)1/50 (2%)30/50 (60%)31/50 (62%)0/50 (0%)28/50 (56%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 1.63% Total 89/150 (59.33%) Mean 59.33%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 203

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mesentery: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mesentery: Hemangiosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Mesentery: Lipoma 0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% ...... #Mesentery: Schwannoma Malignant 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Nose: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 204

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Nose: Squamous Cell Carcino	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous o	. •	ynx, Tooth, Gingiva):						
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Squamous Cell Carcino Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%	Total	0/50 (0%) 0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma		0/50 (40/)		0/50 (00()		4/50 (00/)
		1/50 (2%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)
Overell In eldense	Tatal	0/50 (0%)	Mana 0 50/	CD 40/	Tatal	0/50 (0%)	Maara 00/	CD 00%
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 205

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% ..... \*Ovary: **Fibrosarcoma** 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 0/50 (0%)(0%)

0/50

0/50

2/50

2/150 (1.33%)

0/150 (0%)

Total

Total

(0%)

(0%)

(4%)

Mean 0%

Mean 1.33%

SD 0%

SD 2.31%

(0%)

0/50

.....

**Granulosa Cell Tumor Malignant** 

**Overall Incidence** 

**Overall Incidence** 

\*Ovary:

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 206

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
			0/50 (0%) 2/50 (4%)		0/50 (0%)
Overall Incidence		Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Ovary:					
Granulosa-Theca Tumor Benign			1/50 (2%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Ovary: Granulosa-Theca Tumor Malignant					
<b>3</b>			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
Ovary: Schwannoma Malignant				•••••	
<b>3</b>			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Pancreas: Adenoma 0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)2/50 (4%)0/48 (0%)**Overall Incidence** Total 2/198 (1.01%) Mean 1% SD 2% Total 0/146 (0%) Mean 0% SD 0% \*Pancreas: Carcinoma 0/49(0%)0/49 (0%)0/50 (0%)0/49(0%)0/49 (0%)0/50 (0%)0/48 (0%)Mean 0% Overall Incidence Total 0/198 (0%) SD 0% Total 0/146 (0%) Mean 0% SD 0% ...... \*Pancreas: Carcinoma or Adenoma 0/49 (0%)0/49 0/50 (0%)0/49 (0%)0/49 (0%)2/50 (4%)0/48 (0%)**Overall Incidence** Total 2/198 (1.01%) Mean 1% SD 2% Total 0/146 (0%) Mean 0% SD 0% \*Pancreas: **Mixed Tumor Benign** 0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/198 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% \*Pancreas: **Mixed Tumor Malignant** 0/49 (0%)0/49 (0%)1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/146 (0%) Mean 0% SD 0%

.....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 208

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Parathyroid Gland: Adenoma 1/45 (2%)1/46 (2%)0/49 (0%)0/48 (0%)0/49 (0%)0/49 0/50 (0%)(0%)Mean 0% **Overall Incidence** Total 2/190 (1.05%) Mean 1.1% SD 1.27% Total 0/146 (0%) SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 10/50 (20%)20/50 (40%)8/50 (16%)24/49 (49%)(50%)13/50 (26%)20/50 (40%)Overall Incidence Total 51/200 (25.5%) Mean 25.5% SD 10.5% Total 69/149 (46.31%) Mean 46.33% SD 5.5% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 0/50 1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 2/149 (1.34%) Mean 1.35% SD 1.17% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 10/50 (20%)20/50 (40%)8/50 (16%)25/49 (51%)25/50 (50%)13/50 (26%)21/50 (42%)**Overall Incidence** Total 51/200 (25.5%) Mean 25.5% SD 10.5% Total 71/149 (47.65%) Mean 47.67% SD 4.94% \*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Inte	rmedia:							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intel Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nerv Craniopharyngioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 210

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Salivary Glands: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/197 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Salivary Glands: Sarcoma 0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Salivary Glands: Schwannoma Malignant 0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/50 (0%)Overall Incidence Total 0/197 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Skin: **Basal Cell Adenoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 212

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 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%)1/50 (2%)0/50 (0%)0/50 (0%)1/150 (0.67%) **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total Mean 0.67% SD 1.15% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% 0/150 (0%) SD 0% Total Mean 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/150 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 213

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 4/50 (8%)2/50 0/50 (0%)1/50 (2%)(2%)(4%)(12%) 6/50 1/50 (2%)Overall Incidence Total 13/200 (6.5%) Mean 6.5% SD 4.43% Total 2/150 (1.33%) Mean 1.33% SD 1.15% #Skin: Fibroma 4/50 (8%)1/50 (2%)5/50 (10%)0/50 (0%)1/50 (2%)3/50 (6%)1/50 (2%)13/200 (6.5%) SD 3.42% 2/150 (1.33%) SD 1.15% **Overall Incidence** Total Mean 6.5% Total Mean 1.33% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (8%)(8%) (10%)0/50 (0%)3/50 (6%)(8%) (2%)4/50 1/50 **Overall Incidence** Total 17/200 (8.5%) Mean 8.5% SD 1% Total 4/150 (2.67%) Mean 2.67% SD 3.06% #Skin: **Fibrosarcoma** 0/50 (0%)2/50 0/50 (0%)0/50 (0%)0/50 (0%)(4%)(2%)0/50 (0%)1/50 **Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)3/50 0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/200 (2%) Mean 2% SD 2.83% Total 3/150 (2%) Mean 2% SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
tSkin: 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	0/200 (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%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Keratoacanthoma								
		3/50 (6%) 4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	10/200 (5%)	Mean 5%	SD 2.58%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Lipoma	•							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Neural Crest Tumor, Ma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwi								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or								
	`	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Sarcoma (0%) 0/50 (0%)1/50 (2%)0/50 0/50 2/50 (4%)1/50 (2%)0/50 (0%)Overall Incidence Total 2/200 (1%) Mean 1% SD 1.15% Total 2/150 (1.33%) Mean 1.33% SD 2.31% ...... #Skin: Schwannoma Benign 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Schwannoma 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 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 1/150 (0.67%) Mean 0.67% SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

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Report Date: 05/18/2011

			Male				Female		
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin: Squamous Cell Papillo	oma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillo	oma or Papilloma		2/52 (221)	2/22 (221)		0/50		2/22 (22)	
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillo	oma, Papilloma, S	Squamous Cell Carcinom 3/50 (6%) 6/50 (12%)	a or Keratoacanthom 1/50 (2%)	<b>a</b> 2/50 (4%)		0/50 (0%) 1/50 (2%)		0/50 (0%)	
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin: Squamous Cell Papillo	oma, Papilloma, c		4/50 (001)	0/50 (404)		0/50 (00/)		0/50 (00/)	
		3/50 (6%) 5/50 (10%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	Total	0/150 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male	Female
#Skin: Trichoepithelioma				
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
#Skin: Sebaceous Gland: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (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%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Spinal Cord: Astrocytoma 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	0/200 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female #Spinal Cord: Glioma 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 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Spleen: **Fibrosarcoma** 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)Mean 0% **Overall Incidence** Total 0/198 (0%) SD 0% Total 0/148 (0%) Mean 0% SD 0% \*Spleen: **Fibrous Histiocytoma** 0/50 (0%)0/49 1/49 (2%)0/50 (0%)0/49 (0%)(0%)0/50 0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.51% SD 1.02% Total 0/148 (0%) Mean 0% SD 0% \*Spleen: Hemangiosarcoma 0/49 1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/148 (0%) Mean 0% SD 0% \*Spleen: Leiomyosarcoma 1/50 (2%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/198 (0.51%) Mean 0.5% SD 1% Total 0/148 (0%) Mean 0% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male			Female
*Spleen: Sarcoma						
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total 0/148 (0%)	Mean 0% SD 0%
#Stomach, Forestomach: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
#Stomach, Forestomach: Squamous Cell Papilloma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	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%)		0/50 (0%)
Overall Incidence	Total	0/200 (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%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		46/50 (92%) 46/50 (92%)	49/50 (98%)	42/50 (84%)				
Overall Incidence	Total	183/200 (91.5%)	Mean 91.5%	SD 5.74%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 222

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Testes: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% \*Thymus: **Thymoma Benign** 0/48(0%)(0%)1/48 (2%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)Overall Incidence Total 1/184 (0.54%) Mean 0.52% SD 1.04% Total 0/145 (0%) Mean 0% SD 0% \*Thymus: **Thymoma Malignant** 0/48 (0%)0/47 0/48 (0%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 0/184 (0%) Mean 0% SD 0% Total 0/145 (0%) Mean 0% SD 0% \*Thymus: **Thymoma NOS** 0/49 0/48 (0%)0/47 (0%)0/48 (0%)0/46 (0%)(0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 0/184 (0%) Mean 0% SD 0% Total 0/145 (0%) Mean 0% SD 0% \*Thymus: Thymoma: Benign, Malignant, NOS 0/48 (0%)0/47 (0%)1/48 (2%)0/46 (0%)0/49 (0%)0/41 (0%)0/50 (0%)**Overall Incidence** Total 1/184 (0.54%) Mean 0.52% SD 1.04% Total 0/145 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 223

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 5/48 (10%)	6/50 (12%)	7/50 (14%)		3/49 (6%) 2/47 (4%)		4/50 (8%)
Overall Incidence	Total	23/198 (11.62%)	Mean 11.6%	SD 1.81%	Total	9/146 (6.16%)	Mean 6.13%	SD 1.87%
Thyroid Gland: C-Cell: Carcinoma								
		4/50 (8%) 1/48 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/47 (0%)		1/50 (2%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.52%	SD 2.99%	Total	2/146 (1.37%)	Mean 1.35%	SD 1.17%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		9/50 (18%) 6/48 (13%)	7/50 (14%)	8/50 (16%)		4/49 (8%) 2/47 (4%)		5/50 (10%)
Overall Incidence	Total	30/198 (15.15%)	Mean 15.12%	SD 2.39%	Total	11/146 (7.53%)	Mean 7.47%	SD 2.93%
Thyroid Gland: Follicular Cell: Adenoma								
		2/50 (4%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/47 (0%)		0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/47 (2%)		0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

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Report Date: 05/18/2011

1/50

1/50

SD 1.15%

SD 1.15%

Mean 0.67%

Mean 0.67%

(2%)

(2%)

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 2/50 (4%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)1/47 (2%)Overall Incidence Total 2/198 (1.01%) Mean 1% SD 2% Total 1/146 (0.68%) Mean 0.71% SD 1.23% **#Tissue NOS:** Paraganglioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Mean 0.5% Overall Incidence Total 1/200 (0.5%) SD 1% Total 0/150 (0%) Mean 0% SD 0% #Tongue: **Squamous Cell Carcinoma** 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous

1/50

SD 1%

1/50

SD 1%

(2%)

(2%)

0/50

0/50

0/50

0/50

1/150 (0.67%)

1/150 (0.67%)

Total

Total

(0%)

(0%)

(0%)

(0%)

Total

Total

(2%)

(2%)

(2%)

(2%)

1/50

3/200 (1.5%)

1/50

1/50

3/200 (1.5%)

0/50

0/50

Mean 1.5%

Mean 1.5%

(0%)

(0%)

**Overall Incidence** 

**Overall Incidence** 

Squamous Cell Papilloma

#Tongue:

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 225

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Tooth: Adamantinoma 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Urinary Bladder: **Papilloma** 0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.51% SD 1.02% Total 0/150 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 227

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male			Female	
#Uterus:					
Polyp Stromal			10/50 (20%)		14/50 (28%)
			10/50 (20%)		14/50 (20/0)
Overall Incidence		Total	34/150 (22.67%)	Mean 22.67%	SD 4.62%
Uterus: Sarcoma					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal					
<b></b>			10/50 (20%) 10/50 (20%)		14/50 (28%)
Overall Incidence		Total	34/150 (22.67%)	Mean 22.67%	SD 4.62%
fUterus: Schwannoma Malignant					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 228

Report Date: 05/18/2011

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #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%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% #Vagina: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Zymbal's Gland: Adenoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 1/150 (0.67%) Mean 0.67% SD 1.15%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 229

Report Date: 05/18/2011

			Male			Female	
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%	0/50 (0%) Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied