

NTP Historical Controls Report

All Routes and Vehicles

Wistar Han RATS

November 2014

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
М3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male			Female	
M1	M2	М3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 3

Report Date: 11/11/2014

Species: RATS
Strain: Wistar Han

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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		
Battelle Northwest	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Columbus Laboratory	052020303	07/18/07	727	50(3)	35(687)	632.7	Green tea extract
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	729	50(5)	36(696)	622.2	Metal working fluids (Trim VX)
Southern Research Institute	052020903	08/26/08	729	49(3)	36(671)	673.4	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A
					Female		
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green tea extract
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052052303	07/20/09	731	50(5)	30(681)	391.1	Metal working fluids (Trim VX)
Southern Research Institute	052020903	08/26/08	732	50(5)	37(678)	389.6	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
		34/50 (68%)	26/50 (52%)	32/50 (64%)		33/50 (66%)	38/50 (76%)	42/50 (84%)
		24/50 (48%)	33/49 (67%)	30/50 (60%)		42/50 (84%)	37/50 (74%)	38/50 (76%)
verall Incidence	Total	179/299 (59.87%)	Mean 59.89%	SD 8.27%	Total	230/300 (76.67%)	Mean 76.67%	SD 6.77%
All Organs: Malignant Tumors								
		6/50 (12%)	12/50 (24%)	13/50 (26%)		17/50 (34%)	16/50 (32%)	11/50 (22%)
		4/50 (8%)	13/49 (27%)	8/50 (16%)		13/50 (26%)	10/50 (20%)	10/50 (20%)
verall Incidence	Total	56/299 (18.73%)	Mean 18.76%	SD 7.87%	Total	77/300 (25.67%)	Mean 25.67%	SD 6.12%
#All Organs: Malignant and Benign T		36/50 (72%) 26/50 (52%)	36/50 (72%) 36/49 (73%)	37/50 (74%) 34/50 (68%)		40/50 (80%) 47/50 (94%)	43/50 (86%) 40/50 (80%)	43/50 (86%) 40/50 (80%)
Overall Incidence	Total	205/299 (68.56%)	Mean 68.58%	SD 8.39%	Total	253/300 (84.33%)	Mean 84.33%	SD 5.57%
All Organs: Hemangioma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	1/50 (2%)	1/49 (2%)	1/50 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		3/50 (6%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	8/49 (16%)	3/50 (6%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	17/299 (5.69%)	Mean 5.72%	SD 5.97%	Total	8/300 (2.67%)	Mean 2.67%	SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

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Report Date: 11/11/2014

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 11/11/2014

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Species: RATS
Strain: Wistar Han

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female				
#All Organs: Hemangiosarcoma or Hemangioma											
		4/50 (8%	, , ,	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	1/50 (2% 21/299 (7.02%)	9/49 (18%) Mean 7.06%	4/50 (8%) SD 6.42%	Total	0/50 (0%) 8/300 (2.67%)	2/50 (4%) Mean 2.67%	2/50 (4%) SD 1.63%			
#All Organs: Histiocytic Sarcoma	•••••										
		0/50 (0%	, , ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	6) 0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%			
overali incidence	ıotaı	0/299 (0%)	wean 0%	SD 0%	rotai	2/300 (0.67%)	wean 0.67%	SD 1.63%			
#All Organs: Leukemia: Lvmphocvti	ic. Monocytic. N	Iononuclear, or Undi	ferentiated								
Leukemia: Lymphocyti	ic, Monocytic, N	lononuclear, or Undit 1/50 (2% 0/50 (0% 3/299 (1%)	0/50 (0%)	0/50 (0%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%			
Leukemia: Lymphocyti Overall Incidence #All Organs:	Total	1/50 (2% 0/50 (0% 3/299 (1%)	0) 0/50 (0%) 6) 1/49 (2%) Mean 1.01%	1/50 (2%) SD 1.1%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)			
Leukemia: Lymphocyti Overall Incidence #All Organs:	Total	1/50 (2% 0/50 (0% 3/299 (1%)	o) 0/50 (0%) b) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce	1/50 (2%) SD 1.1%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)			
Leukemia: Lymphocyti Overall Incidence #All Organs:	Total	1/50 (2% 0/50 (0% 3/299 (1%) nphocytic, Mixed, NC	o) 0/50 (0%) b) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce b) 0/50 (0%)	1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Leukemia: Lymphocyti Overall Incidence #All Organs: Malignant Lymphoma:	Total	1/50 (2% 0/50 (0% 3/299 (1%) 	o) 0/50 (0%) b) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce b) 0/50 (0%)	1/50 (2%) SD 1.1% **II Type 0/50 (0%)	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%) SD 0% 2/50 (4%)			
Leukemia: Lymphocyti Overall Incidence #All Organs: Malignant Lymphoma: Overall Incidence	Total Histiocytic, Lyr Total	1/50 (2% 0/50 (0% 3/299 (1%) mphocytic, Mixed, NC 0/50 (0% 1/50 (2% 1/299 (0.33%)	S, or Undifferentiated Ce (a) 0/50 (0%) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce (a) 0/50 (0%) (b) 0/49 (0%) Mean 0.33%	1/50 (2%) SD 1.1% **II Type 0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%) Mean 1.33%	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%) SD 1.63%			
Leukemia: Lymphocyti Overall Incidence #All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Total Histiocytic, Lyr Total	1/50 (2% 0/50 (0% 3/299 (1%) mphocytic, Mixed, NC 0/50 (0% 1/50 (2% 1/299 (0.33%) S	S, or Undifferentiated Ce (a) 0/50 (0%) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce (b) 0/50 (0%) (b) 0/49 (0%) Mean 0.33% (c) 2/50 (4%)	1/50 (2%) SD 1.1% **II Type 0/50 (0%) 0/50 (0%) SD 0.82% 1/50 (2%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%) Mean 1.33%	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%) SD 1.63% 0/50 (0%)			
Leukemia: Lymphocyti Overall Incidence #All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Total Histiocytic, Lyr Total	1/50 (2% 0/50 (0% 3/299 (1%) mphocytic, Mixed, NC 0/50 (0% 1/50 (2% 1/299 (0.33%)	S, or Undifferentiated Ce (a) 0/50 (0%) 1/49 (2%) Mean 1.01% S, or Undifferentiated Ce (b) 0/50 (0%) (b) 0/49 (0%) Mean 0.33% (c) 2/50 (4%)	1/50 (2%) SD 1.1% **II Type 0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 0/300 (0%) 0/50 (0%) 1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%) Mean 1.33%	0/50 (0%) SD 0% 2/50 (4%) 0/50 (0%) SD 1.63%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selection

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Adrenal Cortex: Adenoma								
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 2.34%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Adrenal Cortex: Carcinoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)1/49 (2%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/300 (0.33%) **Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.04% Total Mean 0.33% SD 0.82% *Adrenal Medulla: Pheochromocytoma Benign (8%) (0%)1/49 1/49 (2%)1/50 (2%)4/50 1/50 (2%)(2%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)1/50 (2%)2/49 (4%)Mean 2.01% **Overall Incidence** Total 6/297 (2.02%) SD 3.1% Total 5/297 (1.68%) Mean 1.69% SD 1.53% *Adrenal Medulla: **Pheochromocytoma Complex** 1/49 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.34% SD 0.83% 1/297 (0.34%) Mean 0.33% SD 0.82% Total *Adrenal Medulla: **Pheochromocytoma Malignant** 0/50 0/49 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)1/49 (2%)0/50 (0%)1/49 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.34% SD 0.83% Total 1/297 (0.34%) Mean 0.34% SD 0.83% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 2/49 (4%)1/50 (2%)4/50 (8%)0/49 (0%)1/50 2/49 (4%)

0/49

SD 3.02%

(0%)

Total

0/50

7/297 (2.36%)

(0%)

2/50

(4%)

Mean 2.36%

2/49

(4%)

Total

0/50

8/297 (2.69%)

(0%)

1/49

Mean 2.69%

(2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

Page: 8

Report Date: 11/11/2014

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

Route: ALL ROUTES

Length of Study: CHRONIC

Route: ALL ROUTES

Vehicle: ALL VEHICLES

			Male		Female			
fBlood Vessel: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Bone Marrow: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Bone: Sarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total Mean 0% SD 0% *Brain: Glioma (0%)(0%)0/50 0/50 (0%)2/50 (4%)0/50 0/50 (0%)0/50 (0%)(0%) 0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0.67% Mean 0% Overall Incidence Total 2/299 (0.67%) SD 1.63% Total 0/300 (0%) SD 0% *Brain: **Glioma Malignant** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.04% 0/300 (0%) Mean 0% SD 0% Total *Brain: **Granular Cell Tumor Benign** 0/50 (0%) 1/50 (2%)2/50 (4%)(0%)1/50 (2%)0/50 2/50 (4%)0/50 (0%)1/49 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/299 (1.67%) Mean 1.67% SD 1.51% Total 3/300 (1%) Mean 1% SD 1.67% *Brain: **Granular Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

1/300 (0.33%)

Total

0/299 (0%)

Mean 0%

Overall Incidence

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Mean 0.33%

SD 0.82%

Report Date: 11/11/2014

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

			Male				Female	
*Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Mali	gnant, NOS							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glion	na, or Astroc							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	1/49 (2%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/298 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/298 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 11

Report Date: 11/11/2014

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Heart: Schwannoma Benign 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/300 (0.33%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total Mean 0.33% SD 0.82% *Heart: Schwannoma NOS 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% #Intestine Small: Duodenum: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% 0/300 (0%) Mean 0% SD 0% Total #Intestine Small: Duodenum: Leiomyosarcoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Jejunum: Leiomyoma

0/50

0/50

SD 0%

(0%)

(0%)

1/50

0/50

1/300 (0.33%)

Total

(0%)

0/50

0/50

(0%)

(0%)

Mean 0.33%

0/50

0/50

SD 0.82%

(0%)

(0%)

Total

0/50

0/50

0/299 (0%)

(0%)

(0%)

0/50

0/49

Mean 0%

(0%)

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Site Unspecified: **Fibroma** (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 2/300 (0.67%) Mean 0.67% SD 1.03% *Islets, Pancreatic: Adenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/49 (2%)

1/50

SD 4.54%

(2%)

0/50

1/299 (0.33%)

Total

(0%)

0/50

(0%)

Mean 0.34%

0/50

SD 0.83%

(0%)

Total

5/50

10/299 (3.34%)

(10%)

4/49

Mean 3.36%

(8%)

^{......} *: Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%	Total	0/299 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		5/50 (10%)	6/49 (12%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/299 (4.01%)	Mean 4.04%	SD 5.59%	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%
*Kidney: Pelvis and Transition								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 2%

SD 2.19%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male	Female				
Kidney: Renal Tubule: Carcinoma or Adenoma				-4				
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 2.47%	Total	6/300 (2%)	Mean 2%	SD 2.19%
Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma						
pa.ooonala. oa.onlonia	opa.oo.	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)

SD 2.47%

Total

6/300 (2%)

Mean 1.35%

Total

4/299 (1.34%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female					
Liver:		,										
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)				
		1/50 (2%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 2.47%	Total	6/300 (2%)	Mean 2%	SD 2.19%				
Lung: Alveolar/Bronchiolar A	Adenoma											
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 2.42%	Total	0/300 (0%)	Mean 0%	SD 0%				
•	Carcinoma or Alv	veolar/Bronchiolar ∆deno	ıma									
Lung: Alveolar/Bronchiolar C	Carcinoma or Alv	yeolar/Bronchiolar Adeno 3/50 (6%) 0/50 (0%) 4/299 (1.34%)	0/50 (0%) 0/49 (0%) Mean 1.33%	1/50 (2%) 0/50 (0%) SD 2.42%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%				
Alveolar/Bronchiolar Control Overall Incidence #Lymph Node:		3/50 (6%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Alveolar/Bronchiolar C		3/50 (6%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Alveolar/Bronchiolar Converall Incidence		3/50 (6%) 0/50 (0%) 4/299 (1.34%)	0/50 (0%) 0/49 (0%) Mean 1.33%	0/50 (0%) SD 2.42%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Alveolar/Bronchiolar C Overall Incidence #Lymph Node:		3/50 (6%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%)	0/50 (0%) 0/49 (0%) Mean 1.33%	0/50 (0%) SD 2.42% 0/50 (0%)	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)				
Alveolar/Bronchiolar C Overall Incidence #Lymph Node: Hemangioma Overall Incidence	Total Total	3/50 (6%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%) Mean 1.33% 0/50 (0%) 0/49 (0%)	0/50 (0%) SD 2.42% 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)				
Alveolar/Bronchiolar C Overall Incidence #Lymph Node: Hemangioma Overall Incidence #Lymph Node, Mesenter	Total Total	3/50 (6%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%) Mean 1.33% 0/50 (0%) 0/49 (0%)	0/50 (0%) SD 2.42% 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)				
Alveolar/Bronchiolar C Overall Incidence #Lymph Node: Hemangioma Overall Incidence #Lymph Node, Mesenter	Total Total	3/50 (6%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 1/50 (2%) 1/299 (0.33%)	0/50 (0%) 0/49 (0%) Mean 1.33% 0/50 (0%) 0/49 (0%) Mean 0.33%	0/50 (0%) SD 2.42% 0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Species: RATS
Strain: Wistar Han

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%) 3/50	` ,		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	7/49 (14%) 1/50	` '		0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	13/299 (4.35%)	Mean 4.38% SD 5.3	38%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%) 0/50	` ,		0/50 (0%)	2/50 (4%)	2/50 (4%)
		0/50 (0%)	0/49 (0%) 0/50	` '		4/50 (8%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0	% 	Total	12/300 (4%)	Mean 4%	SD 3.58%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%) 0/50	(0%)		5/50 (10%)	6/50 (12%)	4/50 (8%)
		0/50 (0%)	0/49 (0%) 0/50	(0%)		4/50 (8%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0	%	Total	21/300 (7%)	Mean 7%	SD 4.15%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%) 0/50	` ,		5/50 (10%)	8/50 (16%)	6/50 (12%)
		0/50 (0%)	0/49 (0%) 0/50	` '		8/50 (16%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0	%	Total	32/300 (10.67%)	Mean 10.67%	SD 5.32%
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%) 0/50	` '		7/50 (14%)	11/50 (22%)	9/50 (18%)
		0/50 (0%)	0/49 (0%) 1/50	` '		2/50 (4%)	9/50 (18%)	8/50 (16%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33% SD 0.8	32%	Total	46/300 (15.33%)	Mean 15.33%	SD 6.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Mammary Gland: Fibroma, Fibroadenoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)7/50 (14%)11/50 (22%)11/50 (22%)(24%)0/50 (0%)0/49 (0%)1/50 (2%)(12%)9/50 (18%)12/50 **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 56/300 (18.67%) Mean 18.67% SD 4.84% #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)10/50 (20%)15/50 (30%)13/50 (26%)0/50 (0%)0/49 (0%)1/50 (2%)9/50 (18%)10/50 (20%)12/50 (24%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 69/300 (23%) Mean 23% SD 4.52% #Mesentery: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% Total #Mesentery: Lipoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Schwannoma Malignant 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.82%

Total

0/300 (0%)

Total

1/299 (0.33%)

.....

Mean 0.33%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Nose: Chondroma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%) 0/50 (0%)0/49 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)1/299 (0.33%) 1/299 (0.33%) **Overall Incidence** Total Mean 0.33% SD 0.82% Total Mean 0.33% SD 0.82% *Nose: **Olfactory Neuroblastoma** (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/299 (0.33%) Mean 0.33% SD 0.82% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% 1/300 (0.33%) Mean 0.33% SD 0.82% Total #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma (0%) 0/50 0/50 1/50 (2%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% SD 0.82% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)

0/50

SD 0.82%

(0%)

0/50

1/300 (0.33%)

Total

(0%)

0/50

(0%)

Mean 0.33%

0/50

SD 0.82%

(0%)

Total

0/50

1/299 (0.33%)

(0%)

.....

0/49

Mean 0.33%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 11/11/2014

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	Male		Female	
*Ovary: Adenoma				
		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%
*Ovary: Cystadenoma				
		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
Overall incluence	Total			30 0.02/0
*Ovary: Granulosa Cell Tumor Benign				
		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Tatal	0/50 (0%)	1/50 (2%)	0/50 (0%)
	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Ovary: Granulosa Cell Tumor Malignant				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
, , , , , , , , , , , , , , , , , , ,		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

			Male				Female	
Ovary: Sex Cord Stromal Tumor, I	Benign							
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	2/50 (4%) SD 1.63%
*Ovary:								
Tubulostromal Adenoma						2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
*Pancreas: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	1/46 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/296 (1.35%)	Mean 1.36%	SD 1.06%	Total	0/299 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	1/46 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/296 (1.35%)	Mean 1.36%	SD 1.06%	Total	0/299 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/44 (0%)	0/47 (0%)	0/43 (0%)		0/39 (0%)	0/47 (0%)	0/47 (0%)
		0/39 (0%)	2/47 (4%)	0/45 (0%)		1/42 (2%)	1/49 (2%)	0/48 (0%)
Overall Incidence	Total	2/265 (0.75%)	Mean 0.71%	SD 1.74%	Total	2/272 (0.74%)	Mean 0.74%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 14/50 (28%)17/50 (34%)16/49 (33%)19/50 (38%)32/50 (64%)35/50 (70%)14/50 (28%)19/49 (39%)21/50 (42%)(68%)(46%)21/50 (42%)**Overall Incidence** Total 101/298 (33.89%) Mean 33.9% SD 5.67% Total 164/300 (54.67%) Mean 54.67% SD 14.24% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma (0%) 0/50 (0%)0/50 (0%)0/49 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 14/50 (28%)17/50 (34%)16/49 (33%)20/50 (40%)32/50 (64%)35/50 (70%)14/50 (28%)19/49 (39%)21/50 (42%)(68%)23/50 (46%)21/50 (42%)**Overall Incidence** Total 101/298 (33.89%) Mean 33.9% SD 5.67% 165/300 (55%) Mean 55% SD 13.78% Total *Pituitary Gland: Pars Intermedia: Adenoma 1/50 (2%)1/50 (2%)2/49 (4%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)0/49 (0%)2/50 (4%)1/50 (2%)1/50 (2%)4/50 (8%)Overall Incidence Total 7/298 (2.35%) Mean 2.35% SD 1.52% Total 9/300 (3%) Mean 3% SD 2.76% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 1/50 (2%)1/50 (2%)2/49 (4%)0/50 (0%)2/50 (4%)1/50 (2%)

2/50

SD 1.52%

(4%)

1/50

9/300 (3%)

Total

(2%)

1/50

(2%)

Mean 3%

4/50

SD 2.76%

(8%)

Total

1/50

7/298 (2.35%)

(2%)

0/49

Mean 2.35%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

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Report Date: 11/11/2014

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
*Prostate: Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%				
*Prostate: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%				
*Salivary Glands: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/46 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.36%	SD 0.89%	Total	0/299 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/46 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/46 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.36%	SD 0.89%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

Length of Study: CHRONIC

			Male				Female	
*Salivary Glands: Myoepithelioma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/46 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/296 (0.68%)	Mean 0.67%	SD 1.03%	Total	0/299 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/46 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Report Date: 11/11/2014

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			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	1/49 (2%)	2/50 (4%)	-	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Basal Cell Adenoma or	Basasauamau	s Tumor Ronian						
Dasai Celi Auellollia Ol	Basosquamous	0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.97%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin:	asosquamous 1	Fumor Benign, or Trichoe	epithelioma 2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
#Skin:		Гumor Benign, or Trichoe	epithelioma		Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Skin: Basal Cell Adenoma, Ba Overall Incidence#Skin:	asosquamous 1	Fumor Benign, or Trichoe 0/50 (0%) 0/50 (0%)	epithelioma 2/50 (4%) 1/49 (2%)	0/50 (0%) 2/50 (4%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)
#Skin: Basal Cell Adenoma, Ba Overall Incidence	asosquamous 1	Fumor Benign, or Trichoe 0/50 (0%) 0/50 (0%)	epithelioma 2/50 (4%) 1/49 (2%)	0/50 (0%) 2/50 (4%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)
#Skin: Basal Cell Adenoma, Ba Overall Incidence#Skin:	asosquamous 1	Fumor Benign, or Trichoe 0/50 (0%) 0/50 (0%) 5/299 (1.67%)	epithelioma 2/50 (4%) 1/49 (2%) Mean 1.67%	0/50 (0%) 2/50 (4%) SD 1.97%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
#Skin: Basal Cell Adenoma, Ba Overall Incidence#Skin:	asosquamous 1	Fumor Benign, or Trichoe 0/50 (0%) 0/50 (0%) 5/299 (1.67%) 0/50 (0%)	epithelioma 2/50 (4%) 1/49 (2%) Mean 1.67%	0/50 (0%) 2/50 (4%) SD 1.97%	Total Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)
#Skin: Basal Cell Adenoma, Ba Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total Total	O/50 (0%) 0/50 (0%) 0/50 (0%) 5/299 (1.67%) 0/50 (0%) 0/50 (0%) 2/299 (0.67%)	2/50 (4%) 1/49 (2%) Mean 1.67% 0/50 (0%) 0/49 (0%) Mean 0.67%	0/50 (0%) 2/50 (4%) SD 1.97% 1/50 (2%) 1/50 (2%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
#Skin: Basal Cell Adenoma, Ba Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total Total	Fumor Benign, or Trichoe 0/50 (0%) 0/50 (0%) 5/299 (1.67%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 1/49 (2%) Mean 1.67% 0/50 (0%) 0/49 (0%) Mean 0.67%	0/50 (0%) 2/50 (4%) SD 1.97% 1/50 (2%) 1/50 (2%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)
#Skin: Basal Cell Adenoma, Ba Overall Incidence #Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total Total	7umor Benign, or Trichoe	2/50 (4%) 1/49 (2%) Mean 1.67% 0/50 (0%) 0/49 (0%) Mean 0.67%	0/50 (0%) 2/50 (4%) SD 1.97% 1/50 (2%) 1/50 (2%) SD 1.03%		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 11/11/2014

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Species: RATS Strain: Wistar Han

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		noma, Basosquamous T	umor (benign, maligna	nt or				
NOO, Or monocplaner	ioma	0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.79%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Basal or Sq. Cell Carci	noma, Carcinon	na, Basosq. Tumor (M or eratoacanthoma, Tricho	· B), Basal Cell Adenor					
		1/50 (2%)	6/50 (12%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/49 (6%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	20/299 (6.69%)	Mean 6.69%	SD 5.16%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Fibroma								
		2/50 (4%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	1/49 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%
Overali incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.27%	Total	2/300 (0.67%)	wiean 0.67%	1.03%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	koma, Myxosarcoma, or	Fibrous Histiocytoma					
		2/50 (4%)	1/50 (2%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.34%	SD 1.5%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

#Skin:

#Skin:

#Skin:

#Skin:

#Skin:

Overall Incidence

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total Mean 0% SD 0% Hamartoma (0%) (0%)0/50 1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%) 0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% Total Keratoacanthoma 1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/49 (4%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 11/299 (3.68%) Mean 3.68% SD 2.34% Total 0/300 (0%) Mean 0% SD 0% Lipoma 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)

Total

0/50

2/299 (0.67%)

(0%)

.....

0/49

Mean 0.67%

(0%)

0/50

SD 1.03%

(0%)

0/50

0/300 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Species: RATS
Strain: Wistar Han

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Neurofibrosarcoma or S	Schwannoma (n	nalignant or NOS)						
Neuronbrosurooma or C	onwannoma (i	0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 2.07%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
Neurofibrosarcoma, Ne	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%)	2/50 (4%) 0/49 (0%) Mean 1.33%	0/50 (0%) 2/50 (4%) SD 2.07%	Total	0/50 (0%) 0/50 (0%) 2/300 (0.67%)	2/50 (4%) 0/50 (0%) Mean 0.67%	0/50 (0%) 0/50 (0%) SD 1.63%
overall Incidence	Total	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%)	2/50 (4%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence Skin:	Total	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%)	2/50 (4%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence Skin:	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%)	2/50 (4%) 0/49 (0%) Mean 1.33%	2/50 (4%) SD 2.07%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%
Overall Incidence Skin: Schwannoma Malignan	Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%)	2/50 (4%) SD 2.07%	Total Total	0/50 (0%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%)	0/50 (0%) SD 1.63%
Overall Incidence Skin: Schwannoma Malignan Overall Incidence	Total t Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%)	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%)		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%)	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Schwannoma Malignan Overall Incidence Skin:	Total t Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%)	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%)		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%)	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%)
Overall Incidence Skin: Schwannoma Malignan Overall Incidence Skin:	Total t Total	0/50 (0%) 0/50 (0%) 4/299 (1.34%) 0/50 (0%) 0/50 (0%) 4/299 (1.34%)	2/50 (4%) 0/49 (0%) Mean 1.33% 2/50 (4%) 0/49 (0%) Mean 1.33%	2/50 (4%) SD 2.07% 0/50 (0%) 2/50 (4%) SD 2.07%		0/50 (0%) 2/300 (0.67%) 0/50 (0%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67% 2/50 (4%) 0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63% 0/50 (0%) 0/50 (0%) SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: ALL ROUTES

Vehicle: ALL VEHICLES

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

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Report Date: 11/11/2014

			Male				Female				
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma											
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%			
#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%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	·	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma, Papilloma,	Squamous Cell Carcinom									
		1/50 (2%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
	T	1/50 (2%)	2/49 (4%)	5/50 (10%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	14/299 (4.68%)	Mean 4.68%	SD 3.5%	Total	0/300 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma, Papilloma,	or Keratoacanthoma									
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	2/49 (4%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	13/299 (4.35%)	Mean 4.35%	SD 3.2%	Total	0/300 (0%)	Mean 0%	SD 0%			

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female #Skin: Sebaceous Gland:** Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total Mean 0% SD 0% #Skin: Sebaceous Gland: Carcinoma or Adenoma (0%) (0%) 0/50 1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0.67% **Overall Incidence** Total 2/299 (0.67%) SD 1.03% Total 0/300 (0%) Mean 0% SD 0% *Spleen: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/47 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/297 (0.67%) Mean 0.69% SD 1.07% Total 0/300 (0%) Mean 0% SD 0% #Stomach, Forestomach: **Fibrosarcoma** 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0% #Stomach, Forestomach: Leiomyoma 0/50 (0%)0/50 (0%)1/50 (2%)1/50 0/50 (0%)0/50 (0%)

0/50

SD 0.82%

(0%)

0/50

1/300 (0.33%)

Total

(0%)

0/50

(0%)

Mean 0.33%

0/50

SD 0.82%

(0%)

Total

0/50

1/299 (0.33%)

(0%)

0/49

Mean 0.33%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	a Squamous						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar Han

Toxicology Data Management System

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Report Date: 11/11/2014

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Stomach, Glandular: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		6/50 (12%)	2/50 (4%)	2/50 (4%)				
		0/50 (0%)	2/49 (4%)	0/50 (0%)				
Overall Incidence	Total	12/299 (4.01%)	Mean 4.01%	SD 4.38%				
Testes: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
Thymus: Sarcoma								
		0/41 (0%)	0/49 (0%)	0/40 (0%)		0/46 (0%)	0/49 (0%)	0/48 (0%)
		0/48 (0%)	0/45 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/272 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.33%	SD 0.82%
*Thymus: Thymoma Benign								
		3/41 (7%)	2/49 (4%)	1/40 (3%)		6/46 (13%)	3/49 (6%)	5/48 (10%)
		3/48 (6%)	0/45 (0%)	1/49 (2%)		8/48 (17%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	10/272 (3.68%)	Mean 3.7%	SD 2.74%	Total	23/291 (7.9%)	Mean 8.04%	SD 6.48%
*Thymus: Thymoma: Benign, Maligna	int, NOS							
		3/41 (7%)	2/49 (4%)	1/40 (3%)		6/46 (13%)	3/49 (6%)	5/48 (10%)
		3/48 (6%)	0/45 (0%)	1/49 (2%)		8/48 (17%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	10/272 (3.68%)	Mean 3.7%	SD 2.74%	Total	23/291 (7.9%)	Mean 8.04%	SD 6.48%
*Thyroid Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/45 (0%)	0/50 (0%)		0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%)	4/50 (8%)	7/50 (14%)		4/50 (8%)	3/50 (6%)	3/50 (6%)
		3/50 (6%)	11/45 (24%)	5/50 (10%)		7/49 (14%)	7/45 (16%)	7/50 (14%)
Overall Incidence	Total	35/295 (11.86%)	Mean 12.07%	SD 6.62%	Total	31/294 (10.54%)	Mean 10.64%	SD 4.44%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
O	Tatal	0/50 (0%)	0/45 (0%)	0/50 (0%)	Tatal	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.33%	SD 0.82%	Total	2/294 (0.68%)	Mean 0.67%	SD 1.03%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/50 (12%)	4/50 (8%)	7/50 (14%)		5/50 (10%)	4/50 (8%)	3/50 (6%)
		3/50 (6%)	11/45 (24%)	5/50 (10%)		7/49 (14%)	7/45 (16%)	7/50 (14%)
Overall Incidence	Total	36/295 (12.2%)	Mean 12.41%	SD 6.54%	Total	33/294 (11.22%)	Mean 11.31%	SD 3.87%
*Thyroid Gland: Follicular Cell Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/45 (2%)	3/50 (6%)		0/49 (0%)	1/45 (2%)	3/50 (6%)
Overall Incidence	Total	5/295 (1.69%)	Mean 1.7%	SD 2.35%	Total	7/294 (2.38%)	Mean 2.37%	SD 1.96%
Thyroid Gland: Follicular Cell Carcinoma	:			•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/45 (0%)	0/50 (0%)		1/49 (2%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	3/294 (1.02%)	Mean 1.01%	SD 1.1%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	1/45 (2%)	3/50 (6%)		1/49 (2%)	1/45 (2%)	3/50 (6%)
Overall Incidence	Total	5/295 (1.69%)	Mean 1.7%	SD 2.35%	Total	10/294 (3.4%)	Mean 3.38%	SD 1.59%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female			
*Urinary Bladder: Carcinoma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
*Urinary Bladder: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	
#Uterus: Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	
#Uterus: Carcinoma									
						3/50 (6%)	3/50 (6%)	1/50 (2%)	
						1/50 (2%)	1/50 (2%)	3/50 (6%)	
Overall Incidence					Total	12/300 (4%)	Mean 4%	SD 2.19%	
#Uterus: Granular Cell Tumor Benigr	n								
3						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
#Uterus:				
Hemangiosarcoma				
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
		•••••	•••••	
Uterus: Leiomyosarcoma				
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
		, ,		
Uterus: Malignant Mixed Mullerian Tumor				
manghant mixou munorium rumo.		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus:				
Polyp Stromal				
		2/50 (4%)	3/50 (6%)	5/50 (10%)
		6/50 (12%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	21/300 (7%)	Mean 7%	SD 3.29%
Uterus: Sarcoma Stromal				
oarcoma ou omai		1/50 (2%)	1/50 (2%)	2/50 (4%)
		1/50 (2%)	0/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%
	I Otal	` ,		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
Uterus:				
Sarcoma Stromal or Polyp Stromal				
		3/50 (6%)	4/50 (8%)	6/50 (12%)
		7/50 (14%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	25/300 (8.33%)	Mean 8.33%	SD 3.88%
Uterus:				
Schwannoma Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%
Uterus:				
Squamous Cell Papilloma				
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Vagina:				
Fibrosarcoma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Magina				
₹Vagina: Leiomyoma				
Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
overall incluence		` ,		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Species: RATS Strain: Wistar Han

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

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Report Date: 11/11/2014

		Male			Female			
#Vagina:								
Polyp						0.750 (00.4)	. (=0 (00)	0.750 (00.4)
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied