

TDMS No. 20306 - 03

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)**

**Date Report Reqsted:** 12/13/2005

**Test Type:** 90-DAY

PCN 66/67 COMPARISON STUDY

**Time Report Reqsted:** 09:05:36

**Route:** GAVAGE

**CAS Number:** PCNCOMPARISN

**First Dose M/F:** NA / 10/13/03

**Species/Strain:** RATS/F 344

**Pathologist:** VASCONCELOS, D.

**Lab:** BAT

F1 PCN 66

**C Number:** C20306

**Lock Date:** 10/07/2004

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

**Treatment Groups:** Include 001 0 NG/KG

Include 002 1000 NG/KG 66

Include 003 10,000 NG/KG 66

Include 004 50,000 NG/KG 66

Include 005 100,000 NG/KG 66

Include 006 200,000 NG/KG 66

Test Type: 90-DAY

PCN 66/67 COMPARISON STUDY

Time Report Requested: 09:05:36

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344

Pathologist: VASCONCELOS, D.

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/ KG 66	50,000 NG/ KG 66	100,000 NG /KG 66	200,000 NG /KG 66
<b>Disposition Summary</b>						
Animals Initially in Study	15	10	10	10	10	10
Early Deaths						
Natural Death						2
Survivors						
Terminal Sacrifice	15	10	10	10	10	8
Animals Examined Microscopically	15	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Intestine Large, Colon	(15)	(0)	(0)	(1)	(0)	(10)
Liver	(15)	(10)	(10)	(10)	(10)	(9)
Mesentery	(0)	(0)	(1)	(0)	(0)	(0)
Pancreas	(15)	(10)	(10)	(10)	(10)	(9)
Stomach, Forestomach	(15)	(10)	(10)	(10)	(10)	(9)
Stomach, Glandular	(15)	(0)	(0)	(0)	(0)	(9)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(15)	(0)	(0)	(0)	(0)	(10)
Heart	(15)	(10)	(10)	(10)	(10)	(10)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(15)	(10)	(10)	(10)	(10)	(9)
Pituitary Gland	(15)	(10)	(10)	(10)	(10)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Ovary	(15)	(10)	(10)	(10)	(10)	(9)
Uterus	(15)	(10)	(10)	(10)	(10)	(9)

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: 90-DAY

PCN 66/67 COMPARISON STUDY

Time Report Reqsted: 09:05:36

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344

Pathologist: VASCONCELOS, D.

Lab: BAT

FISCHER 344 RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/ KG 66	50,000 NG/ KG 66	100,000 NG /KG 66	200,000 NG /KG 66
<b>HEMATOPOIETIC SYSTEM</b>						
Lymph Node, Mesenteric	(15)	(10)	(10)	(10)	(10)	(9)
Spleen	(15)	(10)	(10)	(10)	(10)	(9)
Thymus	(15)	(10)	(10)	(10)	(10)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
None						
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung	(15)	(10)	(10)	(10)	(10)	(10)
Cystic Keratinizing Epithelioma, Multiple						1 (10%)
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland	(15)	(10)	(10)	(10)	(10)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(15)	(10)	(10)	(10)	(10)	(9)
Urinary Bladder	(15)	(0)	(0)	(0)	(0)	(9)
<b>SYSTEMIC LESIONS</b>						
Multiple Organs	*(15)	*(10)	*(10)	*(10)	*(10)	*(10)

a - Number of animals examined microscopically at site and number of animals with lesion

**Test Type:** 90-DAY

PCN 66/67 COMPARISON STUDY

**Time Report Reqsted:** 09:05:36

**Route:** GAVAGE

**CAS Number:** PCNCOMPARISN

**First Dose M/F:** NA / 10/13/03

**Species/Strain:** RATS/F 344

**Pathologist:** VASCONCELOS, D.

**Lab:** BAT

<b>FISCHER 344 RATS FEMALE</b>	<b>0 NG/KG</b>	<b>1000 NG/KG 66</b>	<b>10,000 NG/ KG 66</b>	<b>50,000 NG/ KG 66</b>	<b>100,000 NG /KG 66</b>	<b>200,000 NG /KG 66</b>
Thrombus						5 (50%)

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically

Test Type: 90-DAY

PCN 66/67 COMPARISON STUDY

Time Report Requested: 09:05:36

Route: GAVAGE

CAS Number: PCNCOMPARISN

First Dose M/F: NA / 10/13/03

Species/Strain: RATS/F 344

Pathologist: VASCONCELOS, D.

Lab: BAT

FISCHER 344 RATS FEMALE

0 NG/KG

1000 NG/KG  
66

10,000 NG/  
KG 66

50,000 NG/  
KG 66

100,000 NG  
/KG 66

200,000 NG  
/KG 66

### Tumor Summary for Females

Total Animals with Primary Neoplasms (b)

1

Total Primary Neoplasms

1

Total Animals with Benign Neoplasms

1

Total Benign Neoplasms

1

Total Animals with Malignant Neoplasms

Total Malignant Neoplasms

Total Animals with Metastatic Neoplasms

Total Metastatic Neoplasms

Total Animals with Malignant Neoplasms

Uncertain Primary Site

Total Animals with Neoplasms

Uncertain-Benign or Malignant

Total Uncertain Neoplasms

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors