

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
Disposition Summary						
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
ALIMENTARY SYSTEM						
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)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(15)	(0)	(0)	(0)	(0)	(10)
Heart	(15)	(10)	(10)	(10)	(10)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(15)	(10)	(10)	(10)	(10)	(9)
Pituitary Gland	(15)	(10)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
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
HEMATOPOIETIC SYSTEM						
Lymph Node, Mesenteric	(15)	(10)	(10)	(10)	(10)	(9)
Spleen	(15)	(10)	(10)	(10)	(10)	(9)
Thymus	(15)	(10)	(10)	(10)	(10)	(10)
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(15)	(10)	(10)	(10)	(10)	(10)
Cystic Keratinizing Epithelioma, Multiple						1 (10%)
SPECIAL SENSES SYSTEM						
Harderian Gland	(15)	(10)	(10)	(10)	(10)	(10)
URINARY SYSTEM						
Kidney	(15)	(10)	(10)	(10)	(10)	(9)
Urinary Bladder	(15)	(0)	(0)	(0)	(0)	(9)
SYSTEMIC LESIONS						
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

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
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

Time Report Requested: 09:05:36

Route: GAVAGE

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

Species/Strain: RATS/F 344

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