

**Experiment Number:** 20008-01  
**Test Type:** 90-DAY  
**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Milk thistle extract  
**CAS Number:** 84604-20-6

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 09:04:49  
**First Dose M/F:** NA / NA  
**Lab:** SRI

<b>C Number:</b>	C20008
<b>Lock Date:</b>	11/08/2002
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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

Test Compound: Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 10/21/2014

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First Dose M/F: NA / NA

Lab: SRI

F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(1)	(10)	(10)	(10)	(10)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(10)	(10)	(10)	(10)	(10)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(1)	(0)	(0)	(0)	(0)	(1)
Lymph Node, Mandibular	(1)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)

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

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\* Number of animals with any tissue examined microscopically

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First Dose M/F: NA / NA

Lab: SRI

<b>F 344/N Rat MALE</b>	<b>0 PPM</b>	<b>3125 PPM</b>	<b>6250 PPM</b>	<b>12500 PPM</b>	<b>25000 PPM</b>	<b>50000 PPM</b>
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Lacrimal Gland	(1)	(0)	(0)	(0)	(0)	(1)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(10)	(10)	(10)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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\* Number of animals with any tissue examined microscopically

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Lab: SRI

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F 344/N Rat MALE

0 PPM

3125 PPM

6250 PPM

12500 PPM

25000 PPM

50000 PPM

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**Tumor Summary for MALE**

**Total Animals with Primary Neoplasms (b)**

**Total Primary Neoplasms**

**Total Animals with Benign Neoplasms**

**Total Benign Neoplasms**

**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**

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\*\*\*END OF MALE DATA\*\*\*

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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Lab: SRI

F 344/N Rat FEMALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(9)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(10)	(10)	(10)	(7)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Tooth	(1)	(0)	(0)	(0)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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<b>F 344/N Rat FEMALE</b>	<b>0 PPM</b>	<b>3125 PPM</b>	<b>6250 PPM</b>	<b>12500 PPM</b>	<b>25000 PPM</b>	<b>50000 PPM</b>
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(1)	(1)	(1)	(0)	(10)
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Uterus	(10)	(1)	(0)	(2)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(1)	(0)	(2)	(1)	(0)	(0)
Lymph Node, Mandibular	(2)	(0)	(0)	(0)	(0)	(1)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(0)	(0)	(0)	(10)

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

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Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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**F 344/N Rat FEMALE**

**0 PPM**

**3125 PPM**

**6250 PPM**

**12500 PPM**

**25000 PPM**

**50000 PPM**

---

**Tumor Summary for FEMALE**

**Total Animals with Primary Neoplasms (b)**

**Total Primary Neoplasms**

**Total Animals with Benign Neoplasms**

**Total Benign Neoplasms**

**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**

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**\*\* 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

\* Number of animals with any tissue examined microscopically