

**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Melatonin  
**CAS Number:** 73-31-4

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:51:12  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C96013
<b>Lock Date:</b>	02/28/2003
<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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Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/16/2014

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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
<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)	(2)	(0)	(1)	(1)	(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>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
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)
Islets, Pancreatic	(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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Lab: BAT

F 344/N Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(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, 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)	(0)	(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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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Route: GAVAGE

Species/Strain: Rat/F 344/N

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First Dose M/F: NA / NA

Lab: BAT

<b>F 344/N Rat MALE</b>	<b>0 UG/KG</b>	<b>5 UG/KG</b>	<b>50 UG/KG</b>	<b>5000 UG/KG</b>	<b>50,000 UG/KG</b>	<b>200,000 UG/KG</b>
Alveolar/Bronchiolar Adenoma	1 (10%)					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>F 344/N Rat MALE</b>	<b>0 UG/KG</b>	<b>5 UG/KG</b>	<b>50 UG/KG</b>	<b>5000 UG/KG</b>	<b>50,000 UG/KG</b>	<b>200,000 UG/KG</b>
<b>Tumor Summary for MALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>	<b>1</b>					
<b>Total Primary Neoplasms</b>	<b>1</b>					
<b>Total Animals with Benign Neoplasms</b>	<b>1</b>					
<b>Total Benign Neoplasms</b>	<b>1</b>					
<b>Total Animals with Malignant Neoplasms</b>						
<b>Total Malignant Neoplasms</b>						
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain - Benign or Malignant</b>						
<b>Total Uncertain Neoplasms</b>						

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

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

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Lab: BAT

F 344/N Rat FEMALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
<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)	(2)	(2)	(1)	(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>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
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)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)

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\* Number of animals with any tissue examined microscopically

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Lab: BAT

F 344/N Rat FEMALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Parathyroid Gland	(9)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Polyp Stromal	1 (10%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
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)	(0)	(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)
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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<b>F 344/N Rat FEMALE</b>	<b>0 UG/KG</b>	<b>5 UG/KG</b>	<b>50 UG/KG</b>	<b>5000 UG/KG</b>	<b>50,000 UG/KG</b>	<b>200,000 UG/KG</b>
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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<b>F 344/N Rat FEMALE</b>	<b>0 UG/KG</b>	<b>5 UG/KG</b>	<b>50 UG/KG</b>	<b>5000 UG/KG</b>	<b>50,000 UG/KG</b>	<b>200,000 UG/KG</b>
<b>Tumor Summary for FEMALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>	<b>1</b>					
<b>Total Primary Neoplasms</b>	<b>1</b>					
<b>Total Animals with Benign Neoplasms</b>	<b>1</b>					
<b>Total Benign Neoplasms</b>	<b>1</b>					
<b>Total Animals with Malignant Neoplasms</b>						
<b>Total Malignant Neoplasms</b>						
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<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain - Benign or Malignant</b>						
<b>Total Uncertain Neoplasms</b>						

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

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\* Number of animals with any tissue examined microscopically