

Experiment Number: 96013-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/LONG-EVANS

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

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

Date Report Requested: 10/21/2014
Time Report Requested: 08:48:17
First Dose M/F: NA / NA
Lab: BAT

C Number:	C96013
Lock Date:	02/28/2003
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

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CAS Number: 73-31-4

Date Report Requested: 10/21/2014

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First Dose M/F: NA / NA

Lab: BAT

LONG-EVANS Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Disposition Summary						
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
ALIMENTARY SYSTEM						
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)	(0)	(0)	(0)	(0)	(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)	(1)	(0)	(10)
Tooth	(6)	(0)	(0)	(0)	(0)	(3)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(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

LONG-EVANS Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(0)	(10)
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)	(1)	(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)	(2)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(1)
Lymph Node, Mandibular	(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)	(9)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)	(0)
Rhabdomyosarcoma			1 (100%)			

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LONG-EVANS Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
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)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Harderian Gland	(10)	(10)	(10)	(8)	(10)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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* Number of animals with any tissue examined microscopically

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Lab: BAT

LONG-EVANS Rat MALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Tumor Summary for MALE						
Total Animals with Primary Neoplasms (b)			1			
Total Primary Neoplasms			1			
Total Animals with Benign Neoplasms						
Total Benign Neoplasms						
Total Animals with Malignant Neoplasms			1			
Total Malignant Neoplasms			1			
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 MALE DATA

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

b - Primary tumors: all tumors except metastatic tumors

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First Dose M/F: NA / NA

Lab: BAT

LONG-EVANS Rat FEMALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Natural Death			1			
Survivors						
Terminal Sacrifice	10	10	9	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(1)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(0)	(0)	(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)
Tooth	(4)	(0)	(0)	(0)	(0)	(4)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)

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* Number of animals with any tissue examined microscopically

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Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(10)	(9)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(1)	(0)	(0)	(10)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Vagina	(0)	(0)	(1)	(0)	(0)	(0)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(1)	(0)	(0)	(10)
Lymph Node	(0)	(0)	(1)	(0)	(0)	(0)
Lymph Node, Mandibular	(10)	(1)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(1)	(0)	(0)	(10)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(1)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)

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

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Lab: BAT

LONG-EVANS Rat FEMALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(1)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(9)	(10)	(10)	(10)
Harderian Gland	(10)	(10)	(9)	(10)	(10)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(1)	(0)	(0)	(10)

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

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LONG-EVANS Rat FEMALE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	50,000 UG/KG	200,000 UG/KG
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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

**** 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