

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

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

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

Date Report Requested: 10/16/2014
Time Report Requested: 23:50:32
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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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
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)	(2)	(0)	(1)	(1)	(10)
Hepatodiaphragmatic Nodule Inflammation, Chronic	1 3 [1.0]	2		1	1 1 [1.0]	4 [1.0]
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)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	9 [1.0]					9 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)

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

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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)	(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						

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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
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Alveolar Epith, Hyperplasia, Focal	1 [1.0]					
Inflammation, Chronic	8 [1.0]					2 [1.0]
Metaplasia, Osseous						1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Cornea, Inflammation					1 [2.0]	
Retina, Dysplasia			1 [1.0]			
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	1 [1.0]			3 [1.0]		1 [1.0]
Pigmentation	2 [2.0]		1 [2.0]	5 [2.0]	8 [2.0]	10 [2.0]
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	2 [1.0]					4 [1.0]
Nephropathy	9 [1.0]					5 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

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

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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)	(1)	(2)	(2)	(1)	(10)
Hepatodiaphragmatic Nodule	1	1	2	2	1	1
Inflammation, Chronic	8 [1.0]		1 [1.0]			9 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	1 [2.0]					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	7 [1.0]					8 [1.0]
Myocardium, Mineralization	1 [2.0]					

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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
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst						1
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1 [1.0]
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1					
Mineralization		1 [1.0]				
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Dilatation	3 [1.7]	2 [1.0]	3 [1.7]	3 [1.0]	2 [1.0]	
Metaplasia, Squamous	2 [1.0]					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 [1.0]					
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)

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Skin	(10)	(0)	(0)	(0)	(0)	(10)
Lip, Inflammation, Chronic Active	1 [3.0]					
Lip, Ulcer	1 [3.0]					
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
Cranial Nerve, Degeneration	1 [2.0]					
Pineal Gland, Infiltration Cellular, Lymphocyte	1 [1.0]					
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage, Acute						1 [2.0]
Inflammation, Chronic	1 [1.0]					5 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic						1 [1.0]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Retina, Dysplasia						1 [2.0]
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	3 [1.0]					
Pigmentation	1 [2.0]	3 [2.0]	4 [2.0]	5 [2.0]	5 [2.0]	8 [2.1]
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Infarct	1 [1.0]					
Infiltration Cellular, Mononuclear Cl	1 [1.0]					1 [1.0]

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Mineralization	5 [1.0]					4 [1.0]
Nephropathy						2 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

**** END OF REPORT ****

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

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