

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

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:51:04  
**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
<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)
Hepatodiaphragmatic Nodule Inflammation, Chronic	1 (10%) 3 (30%)	2 (100%)		1 (100%)	1 (100%)	4 (40%)
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)
Cardiomyopathy	9 (90%)					9 (90%)
<b>ENDOCRINE SYSTEM</b>						
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

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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
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						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Alveolar Epith, Hyperplasia, Focal	1 (10%)					

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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
Inflammation, Chronic	8 (80%)					2 (20%)
Metaplasia, Osseous						1 (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)
Cornea, Inflammation					1 (10%)	
Retina, Dysplasia			1 (10%)			
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	1 (10%)			3 (30%)		1 (10%)
Pigmentation	2 (20%)		1 (10%)	5 (50%)	8 (80%)	10 (100%)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	2 (20%)					4 (40%)
Nephropathy	9 (90%)					5 (50%)
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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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)
Hepatodiaphragmatic Nodule	1 (10%)	1 (100%)	2 (100%)	2 (100%)	1 (100%)	1 (10%)
Inflammation, Chronic	8 (80%)		1 (50%)			9 (90%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	1 (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)
Cardiomyopathy	7 (70%)					8 (80%)
Myocardium, Mineralization	1 (10%)					
<b>ENDOCRINE SYSTEM</b>						

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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
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 (10%)
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1 (10%)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1 (10%)					
Mineralization		1 (10%)				
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Dilatation	3 (30%)	2 (20%)	3 (30%)	3 (30%)	2 (20%)	
Metaplasia, Squamous	2 (20%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 (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)
Lip, Inflammation, Chronic Active	1 (10%)					

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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
Lip, Ulcer	1 (10%)					
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
Cranial Nerve, Degeneration	1 (10%)					
Pineal Gland, Infiltration Cellular, Lymphocyte	1 (10%)					
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage, Acute						1 (10%)
Inflammation, Chronic	1 (10%)					5 (50%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic						1 (10%)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Retina, Dysplasia						1 (10%)
Harderian Gland	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	3 (30%)					
Pigmentation	1 (10%)	3 (30%)	4 (40%)	5 (50%)	5 (50%)	8 (80%)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Infarct	1 (10%)					
Infiltration Cellular, Mononuclear CI	1 (10%)					1 (10%)
Mineralization	5 (50%)					4 (40%)
Nephropathy						2 (20%)
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 UG/KG**

**5 UG/KG**

**50 UG/KG**

**5000 UG/KG**

**50,000 UG/KG**

**200,000 UG/KG**

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