

**Experiment Number:** 88035-03

**Test Type:** 90-DAY

**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Primidone (primaclone)

**CAS Number:** 125-33-7

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 08:27:35

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

**Lab:** BAT

<b>C Number:</b>	C88035
<b>Lock Date:</b>	03/16/1992
<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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First Dose M/F: NA / NA

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F 344/N Rat MALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<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)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Hepatocyte, Hypertrophy			10 (100%)	10 (100%)	10 (100%)	10 (100%)
Hepatodiaphragmatic Nodule	3 (30%)	1 (10%)	1 (10%)	1 (10%)		
Necrosis						1 (10%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(1)	(10)
Epithelium, Hyperplasia					1 (100%)	1 (10%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(9)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy, Chronic	8 (80%)					4 (40%)
<b>ENDOCRINE SYSTEM</b>						

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

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F 344/N Rat MALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
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)	(8)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst	1 (10%)					
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)
Inflammation, Chronic Active	4 (40%)					8 (80%)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
Germinal Epith, Degeneration	3 (30%)					3 (30%)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
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)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)

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<b>F 344/N Rat MALE</b>	<b>0%</b>	<b>0.03%</b>	<b>0.06%</b>	<b>0.13%</b>	<b>0.25%</b>	<b>0.5%</b>
<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)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
None						
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Nephropathy	9 (90%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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F 344/N Rat FEMALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<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)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Hepatocyte, Hypertrophy			1 (10%)	10 (100%)	10 (100%)	10 (100%)
Hepatodiaphragmatic Nodule	2 (20%)	2 (20%)	2 (20%)	2 (20%)	2 (20%)	2 (20%)
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, Chronic						3 (30%)
<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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Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Craniophar Dct, Pars Distalis, Cyst	2 (20%)					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(2)	(0)	(0)	(1)	(10)
Cyst		2 (100%)			1 (100%)	
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
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)
<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)

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Inflammation, Chronic Active						1 (10%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<hr/>						
SPECIAL SENSES SYSTEM						
<hr/>						
None						
<hr/>						
URINARY SYSTEM						
<hr/>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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