

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:27:05

First Dose M/F: NA / NA

Lab: BAT

C Number:	C88035
Lock Date:	03/16/1992
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%	0.03%	0.06%	0.13%	0.25%	0.5%
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)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Hepatocyte, Hypertrophy			10 [1.0]	10 [2.1]	10 [3.0]	10 [3.0]
Hepatodiaphragmatic Nodule	3	1	1	1		
Necrosis						1 [2.0]
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 [2.0]	1 [2.0]
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(9)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy, Chronic	8 [1.4]					4 [1.0]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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F 344/N Rat MALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
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)	(8)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst	1					
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 [1.3]					8 [1.6]
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
Germinal Epith, Degeneration	3 [1.3]					3 [1.3]
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)

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F 344/N Rat MALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
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)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Nephropathy	9 [1.0]	10 [1.0]	10 [1.2]	10 [1.3]	10 [1.9]	10 [3.0]
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)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Hepatocyte, Hypertrophy			1 [1.0]	10 [2.0]	10 [3.0]	10 [3.0]
Hepatodiaphragmatic Nodule	2	2	2	2	2	2
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, Chronic						3 [1.3]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)

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Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
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					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(2)	(0)	(0)	(1)	(10)
Cyst		2			1	
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
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)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)

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RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
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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