

Experiment Number: 88035-04
Test Type: 90-DAY
Species/Strain: Mouse/B6C3F1

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014

Time Report Requested: 21:18:48

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

Experiment Number: 88035-04

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

Date Report Requested: 10/17/2014

Test Type: 90-DAY

Test Compound: Primidone (primaclone)

Time Report Requested: 21:18:48

Species/Strain: Mouse/B6C3F1

CAS Number: 125-33-7

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse 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						
Moribund Sacrifice						1
Natural Death						2
Survivors						
Terminal Sacrifice	10	10	10	10	10	7
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Gallbladder	(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)	(9)
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%)	7 (70%)
Necrosis	5 (50%)	3 (30%)	1 (10%)	1 (10%)		4 (40%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
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)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)

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

Experiment Number: 88035-04

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

Date Report Requested: 10/17/2014

Test Type: 90-DAY

Test Compound: Primidone (primaclone)

Time Report Requested: 21:18:48

Species/Strain: Mouse/B6C3F1

CAS Number: 125-33-7

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(10)	(10)	(10)
Cytoplasmic Alteration					9 (90%)	8 (80%)
Hypertrophy, Focal				1 (10%)		1 (10%)
Adrenal Medulla	(10)	(0)	(0)	(10)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(0)	(6)
Pituitary Gland	(9)	(0)	(0)	(0)	(0)	(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)
Testes	(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)	(9)
Spleen	(10)	(0)	(0)	(10)	(10)	(10)
Hematopoietic Cell Proliferation					5 (50%)	7 (70%)
Lymph Follic, Atrophy						3 (30%)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy						3 (30%)
INTEGUMENTARY SYSTEM						
Mammary Gland	(3)	(0)	(0)	(0)	(0)	(2)
Skin	(10)	(0)	(0)	(0)	(0)	(10)

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

Experiment Number: 88035-04

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014

Time Report Requested: 21:18:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse 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)
Peripheral Nerve	(0)	(0)	(0)	(0)	(0)	(1)
Spinal Cord	(0)	(0)	(0)	(0)	(0)	(1)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
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

Experiment Number: 88035-04

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

Date Report Requested: 10/17/2014

Test Type: 90-DAY

Test Compound: Primidone (primaclone)

Time Report Requested: 21:18:48

Species/Strain: Mouse/B6C3F1

CAS Number: 125-33-7

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	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						
Moribund Sacrifice						1
Natural Death						1
Survivors						
Terminal Sacrifice	10	10	10	10	10	8
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Gallbladder	(9)	(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)	(8)
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%)	8 (80%)
Necrosis					1 (10%)	1 (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)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Fibrosis						1 (10%)

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

Experiment Number: 88035-04

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

Date Report Requested: 10/17/2014

Test Type: 90-DAY

Test Compound: Primidone (primaclone)

Time Report Requested: 21:18:48

Species/Strain: Mouse/B6C3F1

CAS Number: 125-33-7

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0%	0.03%	0.06%	0.13%	0.25%	0.5%
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Cytoplasmic Alteration						8 (80%)
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(7)	(0)	(0)	(0)	(0)	(8)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(9)
Ovary	(10)	(0)	(1)	(0)	(0)	(10)
Cyst			1 (100%)			
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)	(9)
Spleen	(10)	(0)	(1)	(10)	(10)	(10)
Hematopoietic Cell Proliferation	1 (10%)		1 (100%)	2 (20%)	4 (40%)	10 (100%)
Lymph Follic, Atrophy						2 (20%)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy						2 (20%)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)

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

Experiment Number: 88035-04

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014

Time Report Requested: 21:18:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	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)
Peripheral Nerve	(0)	(0)	(0)	(0)	(0)	(1)
Spinal Cord	(0)	(0)	(0)	(0)	(0)	(1)
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)	(0)	(0)	(0)	(0)	(10)
Nephropathy						2 (20%)
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