

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Primidone (primaclone)

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

**Date Report Requested:** 10/17/2014

**Time Report Requested:** 21:25:28

**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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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PRIMIDONE (PRIMACLONE)**

**MALE MOUSE**

**Organ**

Adrenal Cortex

Liver

Liver: Centrilobular, Hepatocyte

Spleen

Spleen: Lymph Follic

Thymus

**FEMALE MOUSE**

**Organ**

Adrenal Cortex

Liver: Centrilobular, Hepatocyte

Ovary

Spleen

Spleen: Lymph Follic

**Morphology**

Cytoplasmic Alteration

Necrosis

Hypertrophy

Hematopoietic Cell Proliferation

Atrophy

Atrophy

**Morphology**

Cytoplasmic Alteration

Hypertrophy

Cyst

Hematopoietic Cell Proliferation

Atrophy

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Adrenal Cortex</b>						
<b>Cytoplasmic Alteration</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	9/10 (90%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	9/10.00	8/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	90%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	9/10 (90%)	7/7 (100%)
FIRST INCIDENCE	---	---	---	---	92(T)	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.000**	P=0.000**
POLY 1.5	(e)	(e)	(e)	(e)	P=0.000**	P=0.000**
POLY 6	(e)	(e)	(e)	(e)	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.000**	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Adrenal Cortex</b>						
<b>Hypertrophy Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00	0/10.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/10 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	92(T)	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.500	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	P=0.500	(e)	P=0.430
POLY 6	(e)	(e)	(e)	P=0.500	(e)	P=0.430
COCH-ARM / FISHERS	P=0.399	(e)	(e)	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.159	(e)	P=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
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Date Report Requested: 10/17/2014  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Heart</b>						
<b>Fibrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-04

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 1 WEEKS

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 Species/Strain: Mouse/B6C3F1

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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	5/10 (50%)	3/10 (30%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	4/10 (40%)
POLY-3 RATE (b)	5/10.00	3/10.00	1/10.00	1/10.00	0/10.00	4/7.00
POLY-3 PERCENT (g)	50%	30%	10%	10%	0%	57.1%
TERMINAL (d)	5/10 (50%)	3/10 (30%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	4/7 (57%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.554	P=0.329N	P=0.061N	P=0.061N	P=0.008N**	P=0.574
POLY 1.5	P=0.554	P=0.329N	P=0.061N	P=0.061N	P=0.008N**	P=0.576
POLY 6	P=0.554	P=0.329N	P=0.061N	P=0.061N	P=0.008N**	P=0.574
COCH-ARM / FISHERS	P=0.576	P=0.325N	P=0.070N	P=0.070N	P=0.016N*	P=0.500N
MAX-ISO-POLY-3	P=0.126	P=0.189N	P=0.020N*	P=0.020N*	P=0.001N**	P=0.408
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver: Centrilobular, Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	7/7.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	7/7 (100%)
FIRST INCIDENCE	---	92(T)	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=NA	P=NA	P=NA	P=NA	P=0.000**
POLY 1.5	P=0.000**	P=NA	P=NA	P=NA	P=NA	P=0.000**
POLY 6	P=0.000**	P=NA	P=NA	P=NA	P=NA	P=0.000**
COCH-ARM / FISHERS	P=0.192	P=0.000**	P=0.000**	P=0.000**	P=0.000**	P=0.002**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pancreas</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-04  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
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Date Report Requested: 10/17/2014  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Spleen</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	5/10 (50%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	5/10.00	7/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	50%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	5/10 (50%)	7/7 (100%)
FIRST INCIDENCE	---	---	---	---	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.008**	P=0.000**
POLY 1.5	(e)	(e)	(e)	(e)	P=0.008**	P=0.000**
POLY 6	(e)	(e)	(e)	(e)	P=0.008**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.016*	P=0.002**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P<0.001**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

Experiment Number: 88035-04  
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 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Spleen: Lymph Follic Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025*
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Thymus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.059	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-04  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Trachea</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/7.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.569N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.568N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.569N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.243N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
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Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Adrenal Cortex</b>						
<b>Cytoplasmic Alteration</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	8/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.000**
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.000**
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Adrenal Cortex</b>						
<b>Hypertrophy Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-04

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014

Time Report Requested: 21:25:28

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 1 WEEKS

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Heart</b>						
<b>Fibrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	12.5%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/8 (12%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.456
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.456
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.456
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	25%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/8 (25%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.176
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.176
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.176
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.063
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	1/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	12.5%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	1/8 (12%)
FIRST INCIDENCE	---	---	---	---	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.071	(e)	(e)	(e)	P=0.500	P=0.456
POLY 1.5	P=0.071	(e)	(e)	(e)	P=0.500	P=0.456
POLY 6	P=0.071	(e)	(e)	(e)	P=0.500	P=0.456
COCH-ARM / FISHERS	P=0.103	(e)	(e)	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.128	(e)	(e)	(e)	P=0.159	P=0.157
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver: Centrilobular, Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00	10/10.00	8/8.00
POLY-3 PERCENT (g)	0%	0%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	8/8 (100%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	P=NA	P=NA	P=NA	P=0.000**
POLY 1.5	P=0.000**	(e)	P=NA	P=NA	P=NA	P=0.000**
POLY 6	P=0.000**	(e)	P=NA	P=NA	P=NA	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.000**	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
Ovary						
Cyst						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/1.00	0/0.00	0/0.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	100%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	92(T)	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.091	(e)	(e)	(e)
POLY 1.5	(e)	(e)	P=0.091	(e)	(e)	(e)
POLY 6	(e)	(e)	P=0.091	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.408N	(e)	P=0.091	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	P=0.000**	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pancreas</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Spleen</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	1/1 (100%)	2/10 (20%)	4/10 (40%)	10/10 (100%)
POLY-3 RATE (b)	1/10.00	0/0.00	1/1.00	2/10.00	4/10.00	10/10.00
POLY-3 PERCENT (g)	10%	0%	100%	20%	40%	100%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	1/1 (100%)	2/10 (20%)	4/10 (40%)	8/8 (100%)
FIRST INCIDENCE	92(T)	---	92(T)	92(T)	92(T)	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	P=0.146	P=0.500	P=0.148	P=0.000**
POLY 1.5	(e)	(e)	P=0.146	P=0.500	P=0.148	P=0.000**
POLY 6	(e)	(e)	P=0.146	P=0.500	P=0.148	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.182	P=0.500	P=0.152	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	P=0.022*	P=0.274	P=0.059	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
Spleen: Lymph Follic Atrophy						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/1.00	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)	0/10 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.040*	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
Thymus						
Atrophy						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Primidone (primaclone)  
 CAS Number: 125-33-7

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:25:28  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 1 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Trachea</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

**Experiment Number:** 88035-04

**Test Type:** 90-DAY

**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Primidone (primaclone)

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

**Date Report Requested:** 10/17/2014

**Time Report Requested:** 21:25:28

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

**Lab:** BAT

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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