

**Experiment Number:** 88035-03

**Test Type:** 90-DAY

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

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

**Test Compound:** Primidone (primaclone)

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

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

**Time Report Requested:** 08:29:37

**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:** 88035-03

**Test Type:** 90-DAY

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

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

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**Lab:** BAT

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

**MALE RAT**

**Organ**

Heart

Liver

Liver: Centrilobular, Hepatocyte

Prostate

Stomach, Forestomach: Epithelium

**FEMALE RAT**

**Organ**

Heart

Liver: Centrilobular, Hepatocyte

Ovary

**Morphology**

Cardiomyopathy Chronic

Hepatodiaphragmatic Nodule

Hypertrophy

Inflammation Chronic

Hyperplasia

**Morphology**

Cardiomyopathy Chronic

Hypertrophy

Cyst

Experiment Number: 88035-03

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Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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CAS Number: 125-33-7

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Heart</b>						
<b>Cardiomyopathy Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	8/10.00	0/0.00	0/0.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	80%	0%	0%	0%	0%	40%
TERMINAL (d)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.077N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.077N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.077N
COCH-ARM / FISHERS	P=0.055N	(e)	(e)	(e)	(e)	P=0.085N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.029N*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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 RAT(F 344/N)  
LAST REMOVAL AT 14286 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)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%	100%	100%	100%	100%
TERMINAL (d)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.415	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 1.5	P=0.415	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
POLY 6	P=0.415	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.415	P=0.500	P=0.500	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.075	P=0.159	P=0.159	P=0.159	P=0.159	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	3/10 (30%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	1/10.00	1/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	30%	10%	10%	10%	0%	0%
TERMINAL (d)	3/10 (30%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.058N	P=0.292N	P=0.292N	P=0.292N	P=0.095N	P=0.095N
POLY 1.5	P=0.058N	P=0.292N	P=0.292N	P=0.292N	P=0.095N	P=0.095N
POLY 6	P=0.058N	P=0.292N	P=0.292N	P=0.292N	P=0.095N	P=0.095N
COCH-ARM / FISHERS	P=0.059N	P=0.291N	P=0.291N	P=0.291N	P=0.105N	P=0.105N
MAX-ISO-POLY-3	P=0.021N*	P=0.138N	P=0.138N	P=0.138N	P=0.025N*	P=0.025N*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
Liver						
Necrosis						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.075	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 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%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00
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%)	10/10 (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=NA
POLY 1.5	P=0.000**	(e)	P=NA	P=NA	P=NA	P=NA
POLY 6	P=0.000**	(e)	P=NA	P=NA	P=NA	P=NA
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)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Lung</b>						
<b>Inflammation Chronic</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	0/10.00
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%)	0/10 (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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pituitary Gland: Craniophar Dct, Pars Distalis</b>						
<b>Cyst</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	0/10.00
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%)	0/10 (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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pituitary Gland: Pars Distalis</b>						
<b>Cyst</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	0/10.00
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%)	0/10 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Prostate</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	80%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.077
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.077
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.077
COCH-ARM / FISHERS	P=0.055	(e)	(e)	(e)	(e)	P=0.085
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.029*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Stomach, Forestomach: Epithelium</b>						
<b>Hyperplasia</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/1.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.091	P=0.500
COCH-ARM / FISHERS	P=0.352	(e)	(e)	(e)	P=0.091	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Testes: Germinal Epith Degeneration</b>						
<b>LESION RATES</b>						
OVERALL(a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	30%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92(T)	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.678
COCH-ARM / FISHERS	P=0.596	(e)	(e)	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Heart</b>						
<b>Cardiomyopathy Chronic</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%)	3/10 (30%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 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%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
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%)	0/10 (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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	2/10.00	2/10.00	2/10.00	2/10.00	2/10.00
POLY-3 PERCENT (g)	20%	20%	20%	20%	20%	20%
TERMINAL (d)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)	2/10 (20%)
FIRST INCIDENCE	92(T)	92(T)	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.588	P=0.702	P=0.702	P=0.702	P=0.702	P=0.702
POLY 1.5	P=0.588	P=0.702	P=0.702	P=0.702	P=0.702	P=0.702
POLY 6	P=0.588	P=0.702	P=0.702	P=0.702	P=0.702	P=0.702
COCH-ARM / FISHERS	P=0.593	P=0.709N	P=0.709N	P=0.709N	P=0.709N	P=0.709N
MAX-ISO-POLY-3	P=1.000	P=1.000	P=1.000	P=1.000	P=1.000	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
Liver						
Necrosis						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 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%)	1/10 (10%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	10%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
POLY 6	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.500	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.159	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Lung</b>						
<b>Inflammation Chronic</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	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	92(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 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%)	2/2 (100%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	2/2.00	0/0.00	0/0.00	1/1.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
FIRST INCIDENCE	---	92(T)	---	---	92(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=NA	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	P=NA	(e)	(e)	P=0.091	(e)
POLY 6	(e)	P=NA	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.254N	P=0.015*	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	P=0.000**	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pituitary Gland: Craniophar Dct, Pars Distalis</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067N
HISTCONT SAME RTE						
HISTCONT ALL RTEs						
CURR VS HC SAME RTE						
CURR VS HC ALL RTEs						

Experiment Number: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Pituitary Gland: Pars Distalis</b>						
<b>Cyst</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	0/10.00
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%)	0/10 (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: 88035-03

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

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

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014

Time Report Requested: 08:29:37

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0%	0.03%	0.06%	0.13%	0.25%	0.5%
<b>Stomach, Forestomach: Epithelium</b>						
<b>Hyperplasia</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	0/10.00
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%)	0/10 (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:** 88035-03

**Test Type:** 90-DAY

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

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

**Test Compound:** Primidone (primaclone)

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

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

**Time Report Requested:** 08:29:37

**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 \*\***