Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

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

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

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:

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

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

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
	UNCENSORED DEATHS 0  UNCENSORED DEATHS 0	UNCENSORED DEATHS 0 CENSORED DEATHS 0  UNCENSORED DEATHS 0 CENSORED DEATHS 0	UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10  UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

MAIE MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0.25%

TOTAL 10

**UNCENSORED DEATHS 0** 

CENSORED DEATHS 0

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

DOSE = 0.5%

TOTAL 10

UNCENSORED DEATHS 3

**CENSORED DEATHS 0** 

**TERMINAL 7** 

**UNCENSORED DEATH DAYS** 

3 3

CENSORED DEATH DAYS

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

## Male MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

## KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

						(5.43(6)				
DOSE		TIME (DAYS)								
	10	20	30	40	50	60	70	80	90	92(A)
0%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.03%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.06%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.13%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.25%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.5%	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 90-DAY

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014 Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

### Male MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

#### SURVIVAL SUMMARY STATISTICS 0% 0.13% DOSE 0.03% 0.06% SURVIVAL AT END OF STUDY 100.0% 100.0% 100.0% 100.0% (KAPLAN-MEIER) SIGNIFICANCE (B) P=0.002 ----(LIFE TABLE) **MEAN DAY OF NATURAL DEATHS (C)** (STANDARD ERROR) (.) (.) (.) (.) 92.0 **MEAN LIFE SPAN (D)** 92.0 92.0 92.0 (STANDARD ERROR) (0.0)(0.0)(0.0)(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 90-DAY

(STANDARD ERROR)

**MEAN LIFE SPAN (D)** 

(STANDARD ERROR)

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Species/Strain: Mouse/B6C3F1

Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Date Report Requested: 10/17/2014

Lab: BAT

### Male MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

SURVIVAL SUMMARY STATISTICS

### 

(.)

65.3

(13.6)

(.)

92.0

(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

Female MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

1110	TIDOAL CONTITAL TIMEO (DAT	<u> </u>	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
	UNCENSORED DEATHS 0  UNCENSORED DEATHS 0  UNCENSORED DEATHS 0	UNCENSORED DEATHS 0 CENSORED DEATHS 0  UNCENSORED DEATHS 0 CENSORED DEATHS 0  UNCENSORED DEATHS 0 CENSORED DEATHS 0	UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10  UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/17/2014 Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

Female MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0.25%

TOTAL 10 UNCENSORED DEATHS 0

CENSORED DEATHS 0

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

DOSE = 0.5%

TOTAL 10 UNCENSORED DEATHS 2

CENSORED DEATHS 0

**TERMINAL 8** 

**UNCENSORED DEATH DAYS** 

3

**CENSORED DEATH DAYS** 

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

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

Date Report Requested: 10/17/2014 Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

# Female MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

## KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE		TIME (DAYS)								
	10	20	30	40	50	60	70	80	90	92(A)
0%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.03%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.06%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.13%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.25%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.5%	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

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

Date Report Requested: 10/17/2014
Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

## Female MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

## SURVIVAL SUMMARY STATISTICS

DOSE	0%	0.03%	0.06%	0.13%	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)	P=0.022				
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	92.0	92.0	92.0	92.0	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 90-DAY

**Test Compound:** Primidone (primaclone)

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

**Date Report Requested:** 10/17/2014 **Time Report Requested:** 21:16:36

First Dose M/F: NA / NA

Lab: BAT

## Female MOUSE FIRST TERMINAL SACRIFICE AT 92 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	0.25%	0.5%	
SURVIVAL AT END OF STUDY	100.0%	80.0%	
(KAPLAN-MEIER)			
SIGNIFICANCE (B)		P=0.468	
(LIFE TABLE)			
MEAN DAY OF NATURAL DEATHS (C)		3.0	
(STANDARD ERROR)	(.)	(.)	
MEAN LIFE SPAN (D)	92.0	74.2	
(STANDARD ERROR)	(0.0)	(11.9)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Primidone (primaclone)

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

Date Report Requested: 10/17/2014 Time Report Requested: 21:16:36

First Dose M/F: NA / NA

Lab: BAT

\*\* END OF REPORT \*\*

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)