Experiment Number: 88035-03 Test Type: 90-DAY Species/Strain: Rat/F 344/N

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 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

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

# Male RAT FIRST TERMINAL SACRIFICE AT 92 DAYS

	INDIV	IDUAL SURVIVAL TIMES (DAYS)	
DOSE = 0%			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			
DOSE = 0.03%			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			
DOSE = 0.06%			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			
DOSE = 0.13%			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

#### Male RAT 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 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

### Male RAT 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%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

### Male RAT 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)					
(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)	

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

### Male RAT FIRST TERMINAL SACRIFICE AT 92 DAYS

### SURVIVAL SUMMARY STATISTICS

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

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

# Female RAT FIRST TERMINAL SACRIFICE AT 92 DAYS

	INDIV	/IDUAL SURVIVAL TIMES (DAYS)		
DOSE = 0%				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 0.03%				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 0.06%				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 0.13%				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

### Female RAT 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 0	CENSORED DEATHS 0	TERMINAL 10
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

## Female RAT 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%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

### Female RAT 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)				
(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)

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Test Compound: Primidone (primaclone) CAS Number: 125-33-7 Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

## Female RAT FIRST TERMINAL SACRIFICE AT 92 DAYS

# SURVIVAL SUMMARY STATISTICS

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

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

Experiment Number: 88035-03 Test Type: 90-DAY Species/Strain: Rat/F 344/N

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

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

\*\* END OF REPORT \*\*

Date Report Requested: 10/19/2014 Time Report Requested: 08:26:46 First Dose M/F: NA / NA Lab: BAT

(A) FIRST TERMINAL SACRIFICE

(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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE