

TDMS No. 20101 - 02

Test Type: 26-39 WEEKS

Route: DOSED FEED

Species/Strain: MICE/P53(C57BL/6)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Senna (powdered)

CAS Number: 8013-11-4

Date Report Requested: 09/22/2009

Time Report Requested: 13:31:51

First Dose M/F: 06/26/07 / 06/25/07

Lab: BAT

F1_MD

C Number: C20101B
Lock Date: 09/03/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

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Lab: BAT

MALE MICE

FIRST TERMINAL SACRIFICE AT 276 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 ppm

TOTAL 25 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 25

UNCENSORED DEATH DAYS:

None

CENSORED DEATH DAYS:

None

DOSE = 100 ppm

TOTAL 25 UNCENSORED DEATHS 1 CENSORED DEATHS 0 TERMINAL 24

UNCENSORED DEATH DAYS:

231

CENSORED DEATH DAYS:

None

DOSE = 300 ppm

TOTAL 25 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 25

UNCENSORED DEATH DAYS:

None

CENSORED DEATH DAYS:

None

DOSE = 1000 ppm

TOTAL 25 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 25

UNCENSORED DEATH DAYS:

None

CENSORED DEATH DAYS:

None

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MALE MICE

FIRST TERMINAL SACRIFICE AT 276 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 3000 ppm

TOTAL	25	UNCENSORED DEATHS	2	CENSORED DEATHS	0	TERMINAL	23
UNCENSORED DEATH DAYS:							
	256		266				
CENSORED DEATH DAYS:							
	None						

DOSE = 10,000 ppm

TOTAL	25	UNCENSORED DEATHS	1	CENSORED DEATHS	0	TERMINAL	24
UNCENSORED DEATH DAYS:							
	22						
CENSORED DEATH DAYS:							
	None						

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MALE MICE

FIRST TERMINAL SACRIFICE AT 276 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)										
	28	56	84	112	140	168	196	224	252	276(A)	
0 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
100 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0	96.0
300 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1000 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
3000 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	92.0
10,000 ppm	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0

- (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
- (D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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Lab: BAT

MALE MICE

FIRST TERMINAL SACRIFICE AT 276 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 ppm	100 ppm	300 ppm	1000 ppm
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	100.0%	96.0%	100.0%	100.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.657	P=1.000	-----	-----
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	(.)	231.0 (.)	(.)	(.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	276.0 (0.0)	274.2 (1.8)	276.0 (0.0)	276.0 (0.0)

DOSE	3000 ppm	10,000 ppm
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	92.0%	96.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.471	P=1.000
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	261.0 (5.0)	22.0 (.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	274.8 (0.9)	265.8 (10.2)

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

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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Lab: BAT

FEMALE MICE
FIRST TERMINAL SACRIFICE AT 275 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 ppm

TOTAL 25 UNCENSORED DEATHS 2 CENSORED DEATHS 0 TERMINAL 23
UNCENSORED DEATH DAYS:
 225 267
CENSORED DEATH DAYS:
 None

DOSE = 100 ppm

TOTAL 25 UNCENSORED DEATHS 2 CENSORED DEATHS 0 TERMINAL 23
UNCENSORED DEATH DAYS:
 221 261
CENSORED DEATH DAYS:
 None

DOSE = 300 ppm

TOTAL 25 UNCENSORED DEATHS 2 CENSORED DEATHS 0 TERMINAL 23
UNCENSORED DEATH DAYS:
 232 246
CENSORED DEATH DAYS:
 None

DOSE = 1000 ppm

TOTAL 25 UNCENSORED DEATHS 3 CENSORED DEATHS 0 TERMINAL 22
UNCENSORED DEATH DAYS:
 204 209 221
CENSORED DEATH DAYS:
 None

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Lab: BAT

FEMALE MICE
FIRST TERMINAL SACRIFICE AT 275 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 3000 ppm

TOTAL	25	UNCENSORED DEATHS	3	CENSORED DEATHS	0	TERMINAL	22
UNCENSORED DEATH DAYS:							
	71		141		269		
CENSORED DEATH DAYS:							
	None						

DOSE = 10,000 ppm

TOTAL	25	UNCENSORED DEATHS	1	CENSORED DEATHS	0	TERMINAL	24
UNCENSORED DEATH DAYS:							
	264						
CENSORED DEATH DAYS:							
	None						

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FEMALE MICE

FIRST TERMINAL SACRIFICE AT 275 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)									
	28	56	84	112	140	168	196	224	252	275(A)
0 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0	92.0
100 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0	96.0	92.0
300 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	92.0	92.0
1000 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	88.0	88.0	88.0
3000 ppm	100.0	100.0	96.0	96.0	96.0	92.0	92.0	92.0	92.0	88.0
10,000 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0

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FEMALE MICE

FIRST TERMINAL SACRIFICE AT 275 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 ppm	100 ppm	300 ppm	1000 ppm
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	92.0%	92.0%	92.0%	88.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.679N	P=1.000	P=1.000	P=0.940
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	246.0 (21.0)	241.0 (20.0)	239.0 (7.0)	211.3 (5.0)
MEAN LIFE SPAN (D) (STANDARD ERROR)	272.7 (2.0)	272.3 (2.2)	272.1 (2.0)	267.4 (4.3)

DOSE	3000 ppm	10,000 ppm
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	88.0%	96.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.970	P=0.991N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	160.3 (58.0)	264.0 (.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	261.2 (9.6)	274.6 (0.4)

*** END OF REPORT ***

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

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)