

**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)

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**DOSE = 0 ppm**

TOTAL 25                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 25  
UNCENSORED DEATH DAYS:  
None  
CENSORED DEATH DAYS:  
None

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**DOSE = 100 ppm**

TOTAL 25                      UNCENSORED DEATHS 1                      CENSORED DEATHS 0                      TERMINAL 24  
UNCENSORED DEATH DAYS:  
231  
CENSORED DEATH DAYS:  
None

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**DOSE = 300 ppm**

TOTAL 25                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 25  
UNCENSORED DEATH DAYS:  
None  
CENSORED DEATH DAYS:  
None

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**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						

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**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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**Lab:** BAT

**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)	
<b>0 ppm</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>100 ppm</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0	96.0
<b>300 ppm</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>1000 ppm</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>3000 ppm</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	92.0
<b>10,000 ppm</b>	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)

TDMS No. 20101 - 02

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

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

Lab: BAT

MALE MICE

FIRST TERMINAL SACRIFICE AT 276 DAYS

SURVIVAL SUMMARY STATISTICS

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

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

(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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**First Dose M/F:** 06/26/07 / 06/25/07  
**Lab:** BAT

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

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**DOSE = 0 ppm**

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

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**DOSE = 100 ppm**

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

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**DOSE = 300 ppm**

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

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**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						

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**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

- (A) FIRST TERMINAL SACRIFICE
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FEMALE MICE

FIRST TERMINAL SACRIFICE AT 275 DAYS

SURVIVAL SUMMARY STATISTICS

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

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

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

(A) FIRST TERMINAL SACRIFICE

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

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