

**TDMS No.** 20107 - 03  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
N,N-Dimethyl-p-toluidine  
**CAS Number:** 99-97-8

**Date Report Requested:** 01/24/2011  
**Time Report Requested:** 10:59:00  
**First Dose M/F:** 10/20/04 / 10/21/04  
**Lab:** BAT

F1\_R2

**C Number:** C20107  
**Lock Date:** 02/20/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.3.0  
**PWG Approval Date:** NONE

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**MALE RATS**

FIRST TERMINAL SACRIFICE AT 727 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 13                                      CENSORED DEATHS 0                                      TERMINAL 37  
UNCENSORED DEATH DAYS  
337    609    610    610    612    645    664    665    680    680    688    699    710  
CENSORED DEATH DAYS  
None

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**DOSE = 6 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 12                                      CENSORED DEATHS 1                                      TERMINAL 37  
UNCENSORED DEATH DAYS  
324    512    530    588    601    624    674    695    695    713    721    721  
CENSORED DEATH DAYS  
62

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**DOSE = 20 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 18                                      CENSORED DEATHS 1                                      TERMINAL 31  
UNCENSORED DEATH DAYS  
129    233    237    519    538    581    612    616    626    643    645    654    661    680  
686    688    707    712  
CENSORED DEATH DAYS  
147

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**DOSE = 60 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 26                                      CENSORED DEATHS 3                                      TERMINAL 21  
UNCENSORED DEATH DAYS  
348    384    412    431    496    601    612    614    616    622    626    645    645    653  
656    661    661    668    669    671    695    699    723    724    724    724  
CENSORED DEATH DAYS  
192    576    582

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FIRST TERMINAL SACRIFICE AT 727 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	727(A)
0 MG/KG	100.0	100.0	100.0	98.0	98.0	98.0	98.0	98.0	84.0	74.0
6 MG/KG	100.0	100.0	100.0	98.0	98.0	98.0	93.9	89.8	87.8	75.5
20 MG/KG	100.0	98.0	93.9	93.9	93.9	93.9	89.8	87.8	73.5	63.3
60 MG/KG	100.0	100.0	100.0	98.0	93.9	91.8	89.8	87.7	64.1	44.9

(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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**MALE RATS**

FIRST TERMINAL SACRIFICE AT 727 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	74.0%	75.5%	63.3%	44.9%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.001	P=1.000N	P=0.290	P=0.006
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	631.5 (26.5)	616.5 (33.9)	564.8 (41.8)	614.6 (21.2)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	702.2 (9.0)	687.2 (16.4)	657.0 (21.2)	651.9 (16.5)

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Lab: BAT

**FEMALE RATS**

FIRST TERMINAL SACRIFICE AT 728 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 17                                      CENSORED DEATHS 0                                      TERMINAL 33

UNCENSORED DEATH DAYS

547	574	600	625	642	645	646	673	673	685	687	690	691	698
701	701	713											

CENSORED DEATH DAYS

None

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**DOSE = 6 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 7                                      CENSORED DEATHS 1                                      TERMINAL 42

UNCENSORED DEATH DAYS

516	574	611	617	688	701	718							
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CENSORED DEATH DAYS

37

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**DOSE = 20 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 17                                      CENSORED DEATHS 0                                      TERMINAL 33

UNCENSORED DEATH DAYS

604	611	613	613	630	646	659	659	673	680	680	697	705	709
710	714	717											

CENSORED DEATH DAYS

None

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**DOSE = 60 MG/KG**

TOTAL 50                                      UNCENSORED DEATHS 26                                      CENSORED DEATHS 1                                      TERMINAL 23

UNCENSORED DEATH DAYS

14	384	459	468	471	533	537	542	547	583	607	610	612	625
670	681	682	685	694	701	706	714	714	720	720	721		

CENSORED DEATH DAYS

381

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KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	728(A)
0 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0	86.0	66.0
6 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	98.0	95.9	91.8	85.7
20 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	84.0	66.0
60 MG/KG	98.0	98.0	98.0	98.0	96.0	89.8	83.7	79.6	71.5	47.0

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FIRST TERMINAL SACRIFICE AT 728 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	66.0%	85.7%	66.0%	47.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.001	P=0.042N	P=1.000N	P=0.062
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	658.3 (11.6)	632.1 (27.9)	665.9 (9.8)	592.3 (30.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	704.3 (6.1)	700.8 (14.8)	706.9 (5.3)	650.5 (19.0)

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

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