

**Experiment Number:** 20725 - 04  
**Test Type:** CHRONIC  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
2,3-Butanedione  
**CAS Number:** 431-03-8

**Date Report Requested:** 04/15/2016  
**Time Report Requested:** 10:33:43  
**First Dose M/F:** 08/31/09 / 08/31/09  
**Lab:** BNW

F1\_Mice

**NTP Study Number:** C20725  
**Lock Date:** 10/11/2012  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.2.3\_002  
**PWG Approval Date:** 01/25/2016

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**MALE MICE**

FIRST TERMINAL SACRIFICE AT 729 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = Control**

TOTAL 50    UNCENSORED DEATHS 15    CENSORED DEATHS 0    TERMINAL 35  
UNCENSORED DEATH DAYS  
442    519    519    555    590    624    634    641    666    667    674    683    686    697  
722  
CENSORED DEATH DAYS  
None

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**DOSE = 12.5 ppm**

TOTAL 50    UNCENSORED DEATHS 10    CENSORED DEATHS 1    TERMINAL 39  
UNCENSORED DEATH DAYS  
396    480    574    589    611    653    653    676    681    713  
CENSORED DEATH DAYS  
604

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**DOSE = 25 ppm**

TOTAL 50    UNCENSORED DEATHS 13    CENSORED DEATHS 0    TERMINAL 37  
UNCENSORED DEATH DAYS  
320    527    554    588    597    600    637    683    689    706    719    722    723  
CENSORED DEATH DAYS  
None

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**DOSE = 50 ppm**

TOTAL 50    UNCENSORED DEATHS 25    CENSORED DEATHS 0    TERMINAL 25  
UNCENSORED DEATH DAYS  
141    266    320    332    340    407    409    411    477    506    551    560    619    650  
660    665    666    680    688    690    695    717    718    718    723  
CENSORED DEATH DAYS  
None

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**MALE MICE**

FIRST TERMINAL SACRIFICE AT 729 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	729(A)
Control	100.0	100.0	100.0	100.0	100.0	98.0	94.0	90.0	84.0	70.0
12.5 ppm	100.0	100.0	100.0	100.0	98.0	96.0	96.0	92.0	85.9	79.7
25 ppm	100.0	100.0	100.0	98.0	98.0	98.0	96.0	88.0	86.0	74.0
50 ppm	100.0	98.0	96.0	90.0	84.0	82.0	80.0	76.0	68.0	50.0

(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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**MALE MICE**

FIRST TERMINAL SACRIFICE AT 729 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	Control	12.5 ppm	25 ppm	50 ppm
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	70.0%	79.7%	74.0%	50.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.007	P=0.386N	P=0.760N	P=0.049
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	621.3 (20.7)	602.6 (31.2)	620.4 (31.2)	544.4 (34.2)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	696.7 (9.3)	701.2 (9.6)	700.8 (10.4)	636.7 (21.5)

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**FEMALE MICE**

FIRST TERMINAL SACRIFICE AT 731 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = Control**

TOTAL 50                                      UNCENSORED DEATHS 14                                      CENSORED DEATHS 0                                      TERMINAL 36  
UNCENSORED DEATH DAYS  
177    499    587    590    593    647    653    663    663    669    684    687    690    709  
CENSORED DEATH DAYS  
None

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**DOSE = 12.5 ppm**

TOTAL 50                                      UNCENSORED DEATHS 10                                      CENSORED DEATHS 0                                      TERMINAL 40  
UNCENSORED DEATH DAYS  
561    625    635    644    674    680    690    697    703    728  
CENSORED DEATH DAYS  
None

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**DOSE = 25 ppm**

TOTAL 50                                      UNCENSORED DEATHS 8                                      CENSORED DEATHS 0                                      TERMINAL 42  
UNCENSORED DEATH DAYS  
581    592    600    620    620    639    713    714  
CENSORED DEATH DAYS  
None

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**DOSE = 50 ppm**

TOTAL 50                                      UNCENSORED DEATHS 33                                      CENSORED DEATHS 0                                      TERMINAL 17  
UNCENSORED DEATH DAYS  
225    252    260    267    271    320    325    346    347    403    412    424    466    480  
515    547    559    585    596    600    605    646    655    656    669    670    690    690  
696    698    708    710    730  
CENSORED DEATH DAYS  
None

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KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	731(A)
Control	100.0	98.0	98.0	98.0	98.0	98.0	96.0	90.0	82.0	72.0
12.5 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	92.0	80.0
25 ppm	100.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0	88.0	84.0
50 ppm	100.0	100.0	92.0	82.0	76.0	72.0	70.0	58.0	52.0	34.0

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FIRST TERMINAL SACRIFICE AT 731 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	Control	12.5 ppm	25 ppm	50 ppm
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	72.0%	80.0%	84.0%	34.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P<0.001	P=0.415N	P=0.224N	P<0.001
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	607.9 (36.4)	663.7 (15.3)	634.9 (18.3)	515.8 (29.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	696.5 (12.7)	717.5 (4.8)	715.6 (5.7)	589.0 (24.0)

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

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