

**TDMS No.** 99020 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**

Pulegone  
**CAS Number:** 89-82-7

**Date Report Requested:** 02/11/2009  
**Time Report Requested:** 09:57:45  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

F1\_Rev.1\_R2

**C Number:** C99020  
**Lock Date:** 01/06/2006  
**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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**MALE RATS**  
FIRST TERMINAL SACRIFICE AT 727 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 11                      CENSORED DEATHS 0                      TERMINAL 39  
UNCENSORED DEATH DAYS:  
24    29    412    627    632    653    692    699    701    709    723  
CENSORED DEATH DAYS:  
None

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**DOSE = 18.75 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 17                      CENSORED DEATHS 1                      TERMINAL 32  
UNCENSORED DEATH DAYS:  
199    451    570    580    605    611    622    632    638    639    644    672    673    682  
701    709    713  
CENSORED DEATH DAYS:  
374

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**DOSE = 37.5 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 22                      CENSORED DEATHS 0                      TERMINAL 28  
UNCENSORED DEATH DAYS:  
455    456    465    594    598    608    632    636    637    639    641    659    673    675  
682    688    697    701    701    705    724    725  
CENSORED DEATH DAYS:  
None

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**DOSE = 75 MG/KG Stop**

TOTAL 50                      UNCENSORED DEATHS 48                      CENSORED DEATHS 0                      TERMINAL 2

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**MALE RATS**

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

UNCENSORED DEATH DAYS:

360	360	366	366	377	388	393	394	401	407	407	407	407	407
414	414	414	476	490	497	499	502	503	503	510	511	525	532
533	535	539	545	547	561	561	570	587	591	602	605	615	622
634	635	650	673	684	703								

CENSORED DEATH DAYS:

None

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**MALE RATS**  
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)
<b>0 MG/KG</b>	96.0	96.0	96.0	96.0	94.0	94.0	94.0	94.0	88.0	78.0
<b>18.75 MG/KG</b>	100.0	100.0	98.0	98.0	98.0	96.0	96.0	89.8	77.6	65.3
<b>37.5 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	94.0	94.0	90.0	76.0	56.0
<b>75 MG/KG Stop</b>	100.0	100.0	100.0	96.0	66.0	64.0	36.0	20.0	10.0	4.0

- (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 RATS**  
FIRST TERMINAL SACRIFICE AT 727 DAYS

**SURVIVAL SUMMARY STATISTICS**

<b>DOSE</b>	<b>0 MG/KG</b>	<b>18.75 MG/KG</b>	<b>37.5 MG/KG</b>	<b>75 MG/KG Stop</b>
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	78.0%	65.3%	56.0%	4.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P<0.001	P=0.216	P=0.034	P<0.001
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	536.5 (80.3)	608.3 (29.8)	636.0 (17.4)	504.6 (14.2)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	685.1 (20.4)	679.6 (14.2)	686.9 (9.9)	513.5 (14.9)

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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 19                      CENSORED DEATHS 0                      TERMINAL 31  
UNCENSORED DEATH DAYS:  
309 495 502 519 538 581 604 607 634 638 650 659 672 674  
674 674 688 693 721  
CENSORED DEATH DAYS:  
None

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**DOSE = 37.5 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 1                      TERMINAL 37  
UNCENSORED DEATH DAYS:  
561 573 600 637 650 652 670 674 689 701 713 716  
CENSORED DEATH DAYS:  
85

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**DOSE = 75.0 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 0                      TERMINAL 38  
UNCENSORED DEATH DAYS:  
428 497 668 695 698 702 702 702 702 702 708 716  
CENSORED DEATH DAYS:  
None

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**DOSE = 150 MG/KG Stop**

TOTAL 50                      UNCENSORED DEATHS 49                      CENSORED DEATHS 1                      TERMINAL 0  
UNCENSORED DEATH DAYS:  
19 338 349 352 369 390 450 468 470 471 471 488 503 516  
523 524 533 537 538 538 548 550 559 569 574 578 580 582  
586 586 593 593 594 604 604 604 604 607 611 611 617 617  
617 621 643 662 666 666 691

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**FEMALE RATS**  
FIRST TERMINAL SACRIFICE AT 728 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

CENSORED DEATH DAYS:  
393

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FEMALE RATS  
FIRST TERMINAL SACRIFICE AT 728 DAYS

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	98.0	98.0	98.0	90.0	86.0	76.0	62.0
37.5 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.9	87.8	75.5
75.0 MG/KG	100.0	100.0	100.0	100.0	100.0	98.0	96.0	96.0	96.0	76.0
150 MG/KG Stop	98.0	98.0	98.0	92.0	88.0	77.8	59.3	24.6	6.1	0.0

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FIRST TERMINAL SACRIFICE AT 728 DAYS

**SURVIVAL SUMMARY STATISTICS**

<b>DOSE</b>	<b>0 MG/KG</b>	<b>37.5 MG/KG</b>	<b>75.0 MG/KG</b>	<b>150 MG/KG Stop</b>
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	62.0%	75.5%	76.0%	0.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P<0.001	P=0.168N	P=0.104N	P<0.001
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	606.9 (22.7)	653.0 (15.0)	660.0 (27.2)	538.4 (16.3)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	682.0 (11.9)	697.1 (13.7)	711.7 (7.5)	535.5 (16.2)

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

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