

**TDMS No.** 99020 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**

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

**Date Report Requested:** 07/23/2008  
**Time Report Requested:** 09:18:35  
**First Dose M/F:** 04/15/03 / 04/14/03  
**Lab:** BAT

F1\_\_M3

|                             |             |            |            |
|-----------------------------|-------------|------------|------------|
| <b>C Number:</b>            | C99020      |            |            |
| <b>Lock Date:</b>           | 12/21/2005  |            |            |
| <b>Cage Range:</b>          | ALL         |            |            |
| <b>Date Range:</b>          | ALL         |            |            |
| <b>Reasons For Removal:</b> | 25022 ACCK  | 25021 TSAC | 25020 NATD |
|                             | 25019 MSAC  | 25018 DACC |            |
| <b>Removal Date Range:</b>  | ALL         |            |            |
| <b>Treatment Groups:</b>    | Include ALL |            |            |
| <b>Study Gender:</b>        | Both        |            |            |
| <b>TDMSE Version:</b>       | 2.0.0       |            |            |

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**MALE MICE**  
FIRST TERMINAL SACRIFICE AT 730 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 0                      TERMINAL 38  
UNCENSORED DEATH DAYS:  
331 477 479 535 547 549 573 640 641 646 695 714  
CENSORED DEATH DAYS:  
None

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**DOSE = 37.5 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 2                      TERMINAL 36  
UNCENSORED DEATH DAYS:  
444 606 646 646 648 652 688 690 693 693 709 721  
CENSORED DEATH DAYS:  
59 428

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**DOSE = 75 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 8                      CENSORED DEATHS 0                      TERMINAL 42  
UNCENSORED DEATH DAYS:  
588 597 639 646 654 668 695 714  
CENSORED DEATH DAYS:  
None

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**DOSE = 150 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 9                      CENSORED DEATHS 0                      TERMINAL 41  
UNCENSORED DEATH DAYS:  
141 332 473 570 638 640 702 716 718  
CENSORED DEATH DAYS:  
None

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**MALE MICE**  
FIRST TERMINAL SACRIFICE AT 730 DAYS

**KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)**

| DOSE              | TIME (DAYS) |       |       |       |       |       |       |      |      |        |
|-------------------|-------------|-------|-------|-------|-------|-------|-------|------|------|--------|
|                   | 90          | 180   | 270   | 365   | 425   | 485   | 545   | 605  | 665  | 730(A) |
| <b>0 MG/KG</b>    | 100.0       | 100.0 | 100.0 | 98.0  | 98.0  | 94.0  | 92.0  | 86.0 | 80.0 | 76.0   |
| <b>37.5 MG/KG</b> | 100.0       | 100.0 | 100.0 | 100.0 | 100.0 | 97.9  | 97.9  | 97.9 | 87.5 | 75.0   |
| <b>75 MG/KG</b>   | 100.0       | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 96.0 | 90.0 | 84.0   |
| <b>150 MG/KG</b>  | 100.0       | 98.0  | 98.0  | 96.0  | 96.0  | 94.0  | 94.0  | 92.0 | 88.0 | 82.0   |

- (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 730 DAYS

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**SURVIVAL SUMMARY STATISTICS**

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| <b>DOSE</b>   | <b>0 MG/KG</b>  | <b>37.5 MG/KG</b> | <b>75 MG/KG</b> | <b>150 MG/KG</b> |
|---|-----------------|-------------------|-----------------|------------------|
| <b>SURVIVAL AT END OF STUDY</b><br>(KAPLAN-MEIER)             | 76.0%           | 75.0%             | 84.0%           | 82.0%            |
| <b>SIGNIFICANCE (B)</b><br>(LIFE TABLE)                       | P=0.387N        | P=1.000N          | P=0.373N        | P=0.594N         |
| <b>MEAN DAY OF<br/>NATURAL DEATHS (C)</b><br>(STANDARD ERROR) | 568.9<br>(31.2) | 653.0<br>(21.2)   | 650.1<br>(15.4) | 547.8<br>(66.2)  |
| <b>MEAN LIFE SPAN (D)</b><br>(STANDARD ERROR)                 | 691.3<br>(12.2) | 692.1<br>(15.7)   | 717.2<br>(4.8)  | 697.2<br>(15.1)  |

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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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First Dose M/F: 04/15/03 / 04/14/03  
Lab: BAT

**FEMALE MICE**  
FIRST TERMINAL SACRIFICE AT 729 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 MG/KG**

TOTAL 49                      UNCENSORED DEATHS 14                      CENSORED DEATHS 0                      TERMINAL 35  
UNCENSORED DEATH DAYS:  
450 500 598 598 659 663 666 681 683 695 702 710 715 716  
CENSORED DEATH DAYS:  
None

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**DOSE = 37.5 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 9                      CENSORED DEATHS 0                      TERMINAL 41  
UNCENSORED DEATH DAYS:  
493 513 575 624 640 645 666 694 706  
CENSORED DEATH DAYS:  
None

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**DOSE = 75 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 0                      TERMINAL 38  
UNCENSORED DEATH DAYS:  
268 439 541 544 584 631 642 662 667 677 701 714  
CENSORED DEATH DAYS:  
None

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**DOSE = 150 MG/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 1                      TERMINAL 37  
UNCENSORED DEATH DAYS:  
404 566 589 589 591 596 666 670 676 684 703 716  
CENSORED DEATH DAYS:  
2

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Lab: BAT

**FEMALE MICE**  
FIRST TERMINAL SACRIFICE AT 729 DAYS

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**KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)**

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| DOSE              | TIME (DAYS) |       |       |       |       |       |      |      |      |        |
|-------------------|-------------|-------|-------|-------|-------|-------|------|------|------|--------|
|                   | 90          | 180   | 270   | 365   | 425   | 485   | 545  | 605  | 665  | 729(A) |
| <b>0 MG/KG</b>    | 100.0       | 100.0 | 100.0 | 100.0 | 100.0 | 98.0  | 95.9 | 91.8 | 87.8 | 71.4   |
| <b>37.5 MG/KG</b> | 100.0       | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 96.0 | 94.0 | 88.0 | 82.0   |
| <b>75 MG/KG</b>   | 100.0       | 100.0 | 98.0  | 98.0  | 98.0  | 96.0  | 92.0 | 90.0 | 84.0 | 76.0   |
| <b>150 MG/KG</b>  | 100.0       | 100.0 | 100.0 | 100.0 | 98.0  | 98.0  | 98.0 | 87.8 | 87.8 | 75.5   |

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**FEMALE MICE**  
FIRST TERMINAL SACRIFICE AT 729 DAYS

**SURVIVAL SUMMARY STATISTICS**

| <b>DOSE</b>   | <b>0 MG/KG</b>  | <b>37.5 MG/KG</b> | <b>75 MG/KG</b> | <b>150 MG/KG</b> |
|---|-----------------|-------------------|-----------------|------------------|
| <b>SURVIVAL AT END OF STUDY</b><br>(KAPLAN-MEIER)             | 71.4%           | 82.0%             | 76.0%           | 75.5%            |
| <b>SIGNIFICANCE (B)</b><br>(LIFE TABLE)                       | P=1.000N        | P=0.352N          | P=0.857N        | P=0.869N         |
| <b>MEAN DAY OF<br/>NATURAL DEATHS (C)</b><br>(STANDARD ERROR) | 645.4<br>(21.9) | 617.3<br>(25.2)   | 589.2<br>(37.1) | 620.8<br>(24.7)  |
| <b>MEAN LIFE SPAN (D)</b><br>(STANDARD ERROR)                 | 705.1<br>(8.2)  | 708.9<br>(7.5)    | 695.4<br>(12.1) | 688.5<br>(16.5)  |

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

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