

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

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Pulegone
CAS Number: 89-82-7

Date Report Requested: 05/21/2008
Time Report Requested: 09:15:32
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

F1_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: 2.0.0

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

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

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

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

DOSE = 75 CHG 0 MG/KG

TOTAL 50 UNCENSORED DEATHS 48 CENSORED DEATHS 0 TERMINAL 2

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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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KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	727(A)
0 MG/KG	96.0	96.0	96.0	96.0	94.0	94.0	94.0	94.0	88.0	78.0
18.75 MG/KG	100.0	100.0	98.0	98.0	98.0	96.0	96.0	89.8	77.6	65.3
37.5 MG/KG	100.0	100.0	100.0	100.0	100.0	94.0	94.0	90.0	76.0	56.0
75 CHG 0 MG/KG	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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MALE RATS
FIRST TERMINAL SACRIFICE AT 727 DAYS

SURVIVAL SUMMARY STATISTICS

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

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

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

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

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

DOSE = 150 CHG 0 MG/KG

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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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 CHG 0 MG/KG	98.0	98.0	98.0	92.0	88.0	77.8	59.3	24.6	6.1	0.0

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SURVIVAL SUMMARY STATISTICS

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