

Experiment Number: 00058 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/HSD

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 10/25/2018
Time Report Requested: 18:45:05
First Dose M/F: 07/03/12 / 07/02/12
Lab: BAT

Custom Rpt (Litter Based)

NTP Study Number: C00058B
Lock Date: 10/02/2018
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.5.0.0_sfh
PWG Approval Date: NONE

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MALE RATS

FIRST TERMINAL SACRIFICE AT 730 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 mg/kg male

TOTAL 50 [25]	UNCENSORED DEATHS 35					CENSORED DEATHS 0					TERMINAL 15		
UNCENSORED DEATH DAYS													
155	354	481	538	562	573	577	598	599	616	618	621	623	624
631	643	643	646	646	654	666	672	674	676	678	680	692	693
704	711	711	718	718	720	726							
CENSORED DEATH DAYS													
None													

DOSE = 75 mg/kg male

TOTAL 50 [25]	UNCENSORED DEATHS 35					CENSORED DEATHS 0					TERMINAL 15		
UNCENSORED DEATH DAYS													
274	433	447	475	488	553	557	559	560	575	575	596	611	617
618	618	630	637	637	644	653	654	654	666	669	676	680	680
687	706	708	711	713	724	729							
CENSORED DEATH DAYS													
None													

DOSE = 250 mg/kg male

TOTAL 50 [25]	UNCENSORED DEATHS 29					CENSORED DEATHS 0					TERMINAL 21		
UNCENSORED DEATH DAYS													
402	413	435	445	498	521	547	558	589	592	595	604	606	609
616	618	621	664	677	679	682	688	693	694	694	695	711	725
725													
CENSORED DEATH DAYS													
None													

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FIRST TERMINAL SACRIFICE AT 730 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 750 mg/kg male

TOTAL 50 [25]

UNCENSORED DEATHS 34

CENSORED DEATHS 0

TERMINAL 16

UNCENSORED DEATH DAYS

434	441	442	449	502	520	554	564	569	586	598	607	611	613
614	620	632	633	643	643	650	650	653	663	669	672	674	682
693	705	711	713	718	725								

CENSORED DEATH DAYS

None

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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)
0 mg/kg male	100.0	98.0	98.0	96.0	96.0	94.0	92.0	82.0	60.0	30.0
75 mg/kg male	100.0	100.0	100.0	98.0	98.0	92.0	90.0	76.0	54.0	30.0
250 mg/kg male	100.0	100.0	100.0	100.0	96.0	92.0	88.0	76.0	64.0	42.0
750 mg/kg male	100.0	100.0	100.0	100.0	100.0	92.0	88.0	78.0	52.0	32.0

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS. NEGATIVE TRENDS ARE INDICATED BY "N". TREND AND PAIRWISE TESTS USE A PROPORTIONAL HAZARDS MODEL WITH DAMID AS A RANDOM EFFECT.

(C) MEAN OF LITTER MEANS OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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

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MALE RATS

FIRST TERMINAL SACRIFICE AT 730 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	30.0%	30.0%	42.0%	32.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.903	P=0.541	P=0.596N	P=0.747
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	628.0 (17.1)	619.9 (18.8)	612.9 (18.4)	620.1 (12.1)
MEAN LIFE SPAN (D) (STANDARD ERROR)	655.8 (15.3)	647.3 (18.0)	658.5 (15.4)	650.7 (13.7)

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FEMALE RATS

FIRST TERMINAL SACRIFICE AT 729 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 mg/kg female

TOTAL 50 [25] UNCENSORED DEATHS 22 CENSORED DEATHS 0 TERMINAL 28

UNCENSORED DEATH DAYS

499 504 521 524 530 536 556 578 597 600 606 618 655 655
670 677 681 693 706 708 715 719

CENSORED DEATH DAYS

None

DOSE = 75 mg/kg female

TOTAL 50 [25] UNCENSORED DEATHS 26 CENSORED DEATHS 0 TERMINAL 24

UNCENSORED DEATH DAYS

302 332 386 397 482 499 512 570 588 600 605 614 615 629
633 634 648 663 672 675 675 691 712 712 712 726

CENSORED DEATH DAYS

None

DOSE = 250 mg/kg female

TOTAL 50 [25] UNCENSORED DEATHS 21 CENSORED DEATHS 0 TERMINAL 29

UNCENSORED DEATH DAYS

360 488 538 538 578 597 605 608 638 643 644 648 658 668
676 677 690 697 704 715 726

CENSORED DEATH DAYS

None

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FEMALE RATS

FIRST TERMINAL SACRIFICE AT 729 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 750 mg/kg female

TOTAL 50 [25]

UNCENSORED DEATHS 30

CENSORED DEATHS 0

TERMINAL 20

UNCENSORED DEATH DAYS

4	430	475	478	498	501	509	532	540	548	551	570	570	571
578	586	600	600	617	625	629	635	637	641	650	661	675	702
702	719												

CENSORED DEATH DAYS

None

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DOSE	TIME (DAYS)									
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0 mg/kg female	100.0	100.0	100.0	100.0	100.0	100.0	88.0	80.0	72.0	56.0
75 mg/kg female	100.0	100.0	100.0	96.0	92.0	90.0	86.0	78.0	64.0	48.0
250 mg/kg female	100.0	100.0	100.0	98.0	98.0	98.0	92.0	86.0	74.0	58.0
750 mg/kg female	98.0	98.0	98.0	98.0	98.0	92.0	82.0	64.0	48.0	40.0

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SURVIVAL SUMMARY STATISTICS

DOSE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	56.0%	48.0%	58.0%	40.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.056	P=0.398	P=0.784N	P=0.055
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	616.9 (15.8)	586.7 (28.4)	628.9 (16.8)	556.4 (30.3)
MEAN LIFE SPAN (D) (STANDARD ERROR)	679.2 (9.3)	655.6 (15.4)	684.7 (12.5)	632.3 (15.9)

*** END OF REPORT ***

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