

**Experiment Number:** 05117-03  
**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 07:05:34  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C61994C  
**Lock Date:** Not Entered.  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date** 04/27/1994

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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = VEHICLE CONTROL</b>			
TOTAL 30	UNCENSORED DEATHS 2	CENSORED DEATHS 0	TERMINAL 28
<b>UNCENSORED DEATH DAYS</b>			
302	355		
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA0.25/ACETONE</b>			
TOTAL 30	UNCENSORED DEATHS 3	CENSORED DEATHS 0	TERMINAL 27
<b>UNCENSORED DEATH DAYS</b>			
263	297	332	
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA0.25/ TPA 5</b>			
TOTAL 30	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 0
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA 2.5/ACETONE</b>			
TOTAL 29	UNCENSORED DEATHS 2	CENSORED DEATHS 0	TERMINAL 27
<b>UNCENSORED DEATH DAYS</b>			
120	150		
<b>CENSORED DEATH DAYS</b>			
none			

(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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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA2.5/COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 19				CENSORED DEATHS 0			TERMINAL 11			
<b>UNCENSORED DEATH DAYS</b>													
145	196	206	251	266	287	293	295	302	309	312	317	317	323
323	341	342	351	359									
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 2.5/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0			TERMINAL 0			
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ACETONE</b>													
TOTAL 31			UNCENSORED DEATHS 1				CENSORED DEATHS 0			TERMINAL 30			
<b>UNCENSORED DEATH DAYS</b>													
328													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0			TERMINAL 0			
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													

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

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

**Experiment Number:** 05117-03  
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**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 07:05:34  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = BPO 20/ COMPLETE</b>												
TOTAL 30			UNCENSORED DEATHS 7				CENSORED DEATHS 0			TERMINAL 23		
<b>UNCENSORED DEATH DAYS</b>												
27	84	138	139	217	218	297						
<b>CENSORED DEATH DAYS</b>												
none												
<b>DOSE = DMBA 2.5/ BPO 20</b>												
TOTAL 30			UNCENSORED DEATHS 7				CENSORED DEATHS 0			TERMINAL 23		
<b>UNCENSORED DEATH DAYS</b>												
56	293	309	317	342	345	352						
<b>CENSORED DEATH DAYS</b>												
none												
<b>DOSE = DMBA 25/ BPO 20</b>												
TOTAL 30			UNCENSORED DEATHS 13				CENSORED DEATHS 0			TERMINAL 17		
<b>UNCENSORED DEATH DAYS</b>												
174	217	250	251	282	299	302	302	309	334	341	352	359
<b>CENSORED DEATH DAYS</b>												
none												

(A) FIRST TERMINAL SACRIFICE

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

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

**Experiment Number:** 051117-03  
**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 07:05:34  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

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

DOSE	TIME (DAYS)									
	37	74	111	148	185	222	259	296	333	362(A)
VEHICLE CONTROL	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	93.3
DMBA0.25/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	90.0	90.0
DMBA0.25/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 2.5/ACETONE	100.0	100.0	100.0	96.6	93.1	93.1	93.1	93.1	93.1	93.1
DMBA2.5/COMPLETE	100.0	100.0	100.0	96.7	96.7	90.0	86.7	73.3	50.0	36.7
DMBA 2.5/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 25/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.8	96.8
DMBA 25/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
BPO 20/ COMPLETE	96.7	96.7	93.3	86.7	86.7	80.0	80.0	80.0	76.7	76.7
DMBA 2.5/ BPO 20	100.0	96.7	96.7	96.7	96.7	96.7	96.7	93.3	86.7	76.7
DMBA 25/ BPO 20	100.0	100.0	100.0	100.0	96.7	93.3	86.7	83.3	70.0	56.7

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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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**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
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**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

**SURVIVAL SUMMARY STATISTICS**

DOSE	VEHICLE CONTROL	DMBA0.25/ACETONE	DMBA0.25/ TPA 5	DMBA 2.5/ACETONE
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	93.3%	90.0%	100.0%	93.1%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.036	P=0.963	-----	P=1.000
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	328.5 (26.5)	297.3 (19.9)	. (.)	135.0 (15.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	359.8 (2.0)	355.5 (4.0)	. (.)	346.3 (10.9)

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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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**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

**SURVIVAL SUMMARY STATISTICS**

DOSE	DMBA2.5/COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ACETONE	DMBA 25/ TPA 5
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	36.7%	100.0%	96.8%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.000	-----	P=0.969N	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	291.3 (13.0)	. (.)	328.0 (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	317.2 (10.3)	. (.)	360.9 (1.1)	. (.)

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**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

**SURVIVAL SUMMARY STATISTICS**

<b>DOSE</b>	<b>BPO 20/ COMPLETE</b>	<b>DMBA 2.5/ BPO 20</b>	<b>DMBA 25/ BPO 20</b>
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	76.7%	76.7%	56.7%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.122	P=0.138	P=0.002
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	160.0 (34.4)	287.7 (39.5)	290.2 (15.2)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	314.9 (17.6)	344.7 (10.5)	330.9 (9.2)

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**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = VEHICLE CONTROL</b>			
TOTAL 30	UNCENSORED DEATHS 3	CENSORED DEATHS 0	TERMINAL 27
<b>UNCENSORED DEATH DAYS</b>			
22	269	298	
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA0.25/ACETONE</b>			
TOTAL 30	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 29
<b>UNCENSORED DEATH DAYS</b>			
349			
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA0.25/ TPA 5</b>			
TOTAL 30	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 0
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			
<b>DOSE = DMBA 2.5/ACETONE</b>			
TOTAL 31	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 30
<b>UNCENSORED DEATH DAYS</b>			
350			
<b>CENSORED DEATH DAYS</b>			
none			

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**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA2.5/COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 20				CENSORED DEATHS 0			TERMINAL 10			
<b>UNCENSORED DEATH DAYS</b>													
235	250	250	250	251	266	286	298	298	299	310	316	340	341
341	352	352	357	359	359								
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = TPA 5/ COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0			TERMINAL 0			
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 2.5/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0			TERMINAL 0			
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ACETONE</b>													
TOTAL 29			UNCENSORED DEATHS 1				CENSORED DEATHS 0			TERMINAL 28			
<b>UNCENSORED DEATH DAYS</b>													
350													
<b>CENSORED DEATH DAYS</b>													
none													

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**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA 25/ TPA 5</b>																	
TOTAL 30		UNCENSORED DEATHS 0			CENSORED DEATHS 0			TERMINAL 0									
<b>UNCENSORED DEATH DAYS</b>																	
none																	
<b>CENSORED DEATH DAYS</b>																	
none																	
<b>DOSE = BPO 20/ COMPLETE</b>																	
TOTAL 30		UNCENSORED DEATHS 2			CENSORED DEATHS 0			TERMINAL 28									
<b>UNCENSORED DEATH DAYS</b>																	
316		333															
<b>CENSORED DEATH DAYS</b>																	
none																	
<b>DOSE = DMBA 2.5/ BPO 20</b>																	
TOTAL 30		UNCENSORED DEATHS 9			CENSORED DEATHS 0			TERMINAL 21									
<b>UNCENSORED DEATH DAYS</b>																	
182		273		295		295		298		333		334		340		352	
<b>CENSORED DEATH DAYS</b>																	
none																	
<b>DOSE = DMBA 25/ BPO 20</b>																	
TOTAL 30		UNCENSORED DEATHS 7			CENSORED DEATHS 0			TERMINAL 23									
<b>UNCENSORED DEATH DAYS</b>																	
117		120		250		310		320		323		342					
<b>CENSORED DEATH DAYS</b>																	
none																	

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**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

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

DOSE	TIME (DAYS)									
	37	74	111	148	185	222	259	296	333	362(A)
VEHICLE CONTROL	96.7	96.7	96.7	96.7	96.7	96.7	96.7	93.3	90.0	90.0
DMBA0.25/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7
DMBA0.25/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 2.5/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.8
DMBA2.5/COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	83.3	76.7	60.0	33.3
TPA 5/ COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 2.5/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 25/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.6
DMBA 25/ TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
BPO 20/ COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.3	93.3
DMBA 2.5/ BPO 20	100.0	100.0	100.0	100.0	96.7	96.7	96.7	86.7	80.0	70.0
DMBA 25/ BPO 20	100.0	100.0	100.0	93.3	93.3	93.3	90.0	90.0	80.0	76.7

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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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**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 07:05:34  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

**SURVIVAL SUMMARY STATISTICS**

DOSE	VEHICLE CONTROL	DMBA0.25/ACETONE	DMBA0.25/ TPA 5	DMBA 2.5/ACETONE
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	90.0%	96.7%	100.0%	96.8%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.682	P=0.581N	-----	P=0.558N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	196.3 (87.6)	349.0 (.)	. (.)	350.0 (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	345.4 (11.7)	361.6 (0.4)	. (.)	361.6 (0.4)

(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)

**Experiment Number:** 05117-03  
**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 362 DAYS**

**SURVIVAL SUMMARY STATISTICS**

DOSE	DMBA2.5/COMPLETE	TPA 5/ COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ACETONE
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	33.3%	100.0%	100.0%	96.6%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.000	-----	-----	P=0.604N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	305.5 (9.7)	. (.)	. (.)	350.0 (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	324.3 (8.1)	. (.)	. (.)	361.6 (0.4)

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

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

**Experiment Number:** 05117-03  
**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SENCAR

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 07:05:34  
**First Dose M/F:** NA / NA  
**Lab:** BAT

Female MOUSE  
 FIRST TERMINAL SACRIFICE AT 362 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	DMBA 25/ TPA 5	BPO 20/ COMPLETE	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	93.3%	70.0%	76.7%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	P=0.950N	P=0.123	P=0.316
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	.	324.5 (8.5)	300.2 (17.2)	254.6 (36.8)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	.	359.5 (1.8)	343.5 (7.2)	336.9 (11.7)

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

**Experiment Number:** 05117-03  
**Test Type:** INIT/PROMOT  
**Route:** SKIN APPLICATION  
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**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
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**Date Report Requested:** 10/21/2014  
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**\*\* END OF REPORT \*\***

(A) FIRST TERMINAL SACRIFICE

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

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