

**Experiment Number:** 05117-02  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION|SKIN APPLICATION  
**Species/Strain:** Mouse/CD-1 CRL

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 17:46:43  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C61994B  
**Lock Date:** 04/07/1992  
**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 361 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>									
209	276	339							
<b>CENSORED DEATH DAYS</b>									
none									
<b>DOSE = DMBA0.25/ACETONE</b>									
TOTAL 30		UNCENSORED DEATHS 5			CENSORED DEATHS 0			TERMINAL 25	
<b>UNCENSORED DEATH DAYS</b>									
148	222	281	297	360					
<b>CENSORED DEATH DAYS</b>									
none									
<b>DOSE = DMBA0.25/ TPA 5</b>									
TOTAL 30		UNCENSORED DEATHS 10			CENSORED DEATHS 0			TERMINAL 20	
<b>UNCENSORED DEATH DAYS</b>									
138	165	173	209	230	241	295	307	313	342
<b>CENSORED DEATH DAYS</b>									
none									
<b>DOSE = DMBA 2.5/ACETONE</b>									
TOTAL 30		UNCENSORED DEATHS 1			CENSORED DEATHS 0			TERMINAL 29	
<b>UNCENSORED DEATH DAYS</b>									
230									
<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 361 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA2.5/COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 11				CENSORED DEATHS 0			TERMINAL 19			
<b>UNCENSORED DEATH DAYS</b>													
148	250	266	274	292	315	333	357	357	357	357	357		
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = TPA 5/ COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 9				CENSORED DEATHS 0			TERMINAL 21			
<b>UNCENSORED DEATH DAYS</b>													
202	202	274	279	309	313	321	322	351					
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 2.5/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 15				CENSORED DEATHS 0			TERMINAL 15			
<b>UNCENSORED DEATH DAYS</b>													
152	217	230	250	261	292	318	318	320	329	339	343	351	356
357													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ACETONE</b>													
TOTAL 30			UNCENSORED DEATHS 2				CENSORED DEATHS 0			TERMINAL 28			
<b>UNCENSORED DEATH DAYS</b>													
296	326												
<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:** 05117-02  
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**Species/Strain:** Mouse/CD-1 CRL

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
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**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 17:46:43  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA 25/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 15				CENSORED DEATHS 0				TERMINAL 15		
<b>UNCENSORED DEATH DAYS</b>													
159	196	209	245	279	309	309	313	319	319	325	329	343	343
346													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = BPO 20/ COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 5				CENSORED DEATHS 0				TERMINAL 25		
<b>UNCENSORED DEATH DAYS</b>													
258	285	309	315	321									
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 2.5/ BPO 20</b>													
TOTAL 30			UNCENSORED DEATHS 3				CENSORED DEATHS 0				TERMINAL 27		
<b>UNCENSORED DEATH DAYS</b>													
274	322	325											
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ BPO 20</b>													
TOTAL 30			UNCENSORED DEATHS 6				CENSORED DEATHS 0				TERMINAL 24		
<b>UNCENSORED DEATH DAYS</b>													
166	203	222	235	313	322								
<b>CENSORED DEATH DAYS</b>													
none													

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**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 DAYS**

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

DOSE	TIME (DAYS)									
	37	74	111	148	185	222	259	296	333	361(A)
VEHICLE CONTROL	100.0	100.0	100.0	100.0	100.0	96.7	96.7	93.3	93.3	90.0
DMBA0.25/ACETONE	100.0	100.0	100.0	96.7	96.7	93.3	93.3	90.0	86.7	83.3
DMBA0.25/ TPA 5	100.0	100.0	100.0	96.7	90.0	86.7	80.0	76.7	70.0	66.7
DMBA 2.5/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7	96.7
DMBA2.5/COMPLETE	100.0	100.0	100.0	96.7	96.7	96.7	93.3	83.3	76.7	63.3
TPA 5/ COMPLETE	100.0	100.0	100.0	100.0	100.0	93.3	93.3	86.7	73.3	70.0
DMBA 2.5/ TPA 5	100.0	100.0	100.0	100.0	96.7	93.3	86.7	80.0	66.7	50.0
DMBA 25/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	93.3	93.3
DMBA 25/ TPA 5	100.0	100.0	100.0	100.0	96.7	90.0	86.7	83.3	60.0	50.0
BPO 20/ COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	96.7	93.3	83.3	83.3
DMBA 2.5/ BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	90.0	90.0
DMBA 25/ BPO 20	100.0	100.0	100.0	100.0	96.7	90.0	86.7	86.7	80.0	80.0

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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:** 05117-02  
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**Species/Strain:** Mouse/CD-1 CRL

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

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 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%	83.3%	66.7%	96.7%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.061N	P=0.695	P=0.053	P=0.605N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	274.7 (37.5)	261.6 (35.9)	241.3 (22.3)	230.0 (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	352.4 (5.7)	344.4 (8.8)	321.1 (12.7)	356.6 (4.4)

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**Lab:** BAT

**Male MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 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)	63.3%	70.0%	50.0%	93.3%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.037	P=0.105	P=0.002	P=0.975N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	300.5 (19.5)	285.9 (17.6)	295.5 (15.7)	311.0 (15.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	338.8 (8.8)	338.5 (8.2)	328.3 (9.8)	357.7 (2.4)

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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 361 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)	50.0%	83.3%	90.0%	80.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.002	P=0.703	P=1.000N	P=0.437
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	289.5 (15.3)	297.6 (11.6)	307.0 (16.5)	243.5 (25.3)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	325.3 (10.0)	350.4 (4.7)	355.6 (3.3)	337.5 (9.9)

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

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 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>									
237		296							
<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>									
200									
<b>CENSORED DEATH DAYS</b>									
none									
<b>DOSE = DMBA0.25/ TPA 5</b>									
TOTAL 30		UNCENSORED DEATHS 8			CENSORED DEATHS 0			TERMINAL 22	
<b>UNCENSORED DEATH DAYS</b>									
221		267		274		292		313 323 343 343	
<b>CENSORED DEATH DAYS</b>									
none									
<b>DOSE = DMBA 2.5/ACETONE</b>									
TOTAL 30		UNCENSORED DEATHS 1			CENSORED DEATHS 0			TERMINAL 29	
<b>UNCENSORED DEATH DAYS</b>									
193									
<b>CENSORED DEATH DAYS</b>									
none									

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Experiment Number: 05117-02

Test Type: INIT/PROMOT

Route: DERMAL,SOLUTION|SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

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CAS Number: INIT/PROM

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First Dose M/F: NA / NA

Lab: BAT

Female MOUSE  
FIRST TERMINAL SACRIFICE AT 361 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = DMBA2.5/COMPLETE

TOTAL 30                      UNCENSORED DEATHS 10                      CENSORED DEATHS 0                      TERMINAL 20

UNCENSORED DEATH DAYS

225      245      271      286      298      320      321      323      343      349

CENSORED DEATH DAYS

none

DOSE = TPA 5/ COMPLETE

TOTAL 30                      UNCENSORED DEATHS 5                      CENSORED DEATHS 1                      TERMINAL 24

UNCENSORED DEATH DAYS

274      297      297      322      343

CENSORED DEATH DAYS

148

DOSE = DMBA 2.5/ TPA 5

TOTAL 30                      UNCENSORED DEATHS 10                      CENSORED DEATHS 0                      TERMINAL 20

UNCENSORED DEATH DAYS

177      205      263      274      285      296      298      302      329      341

CENSORED DEATH DAYS

none

DOSE = DMBA 25/ACETONE

TOTAL 30                      UNCENSORED DEATHS 1                      CENSORED DEATHS 0                      TERMINAL 29

UNCENSORED DEATH DAYS

169

CENSORED DEATH DAYS

none

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**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

<b>DOSE = DMBA 25/ TPA 5</b>													
TOTAL 30			UNCENSORED DEATHS 14				CENSORED DEATHS 0				TERMINAL 16		
<b>UNCENSORED DEATH DAYS</b>													
204	271	274	279	288	307	315	318	323	323	329	343	349	354
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = BPO 20/ COMPLETE</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0				TERMINAL 30		
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 2.5/ BPO 20</b>													
TOTAL 30			UNCENSORED DEATHS 2				CENSORED DEATHS 0				TERMINAL 28		
<b>UNCENSORED DEATH DAYS</b>													
297	326												
<b>CENSORED DEATH DAYS</b>													
none													
<b>DOSE = DMBA 25/ BPO 20</b>													
TOTAL 30			UNCENSORED DEATHS 0				CENSORED DEATHS 0				TERMINAL 30		
<b>UNCENSORED DEATH DAYS</b>													
none													
<b>CENSORED DEATH DAYS</b>													
none													

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**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 DAYS**

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

DOSE	TIME (DAYS)									
	37	74	111	148	185	222	259	296	333	361(A)
VEHICLE CONTROL	100.0	100.0	100.0	100.0	100.0	100.0	96.7	93.3	93.3	93.3
DMBA0.25/ACETONE	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7	96.7	96.7
DMBA0.25/ TPA 5	100.0	100.0	100.0	100.0	100.0	96.7	96.7	86.7	80.0	73.3
DMBA 2.5/ACETONE	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7	96.7	96.7
DMBA2.5/COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	93.3	86.7	73.3	66.7
TPA 5/ COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.6	86.2	82.8
DMBA 2.5/ TPA 5	100.0	100.0	100.0	100.0	96.7	93.3	93.3	80.0	70.0	66.7
DMBA 25/ACETONE	100.0	100.0	100.0	100.0	96.7	96.7	96.7	96.7	96.7	96.7
DMBA 25/ TPA 5	100.0	100.0	100.0	100.0	100.0	96.7	96.7	83.3	63.3	53.3
BPO 20/ COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DMBA 2.5/ BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.3	93.3
DMBA 25/ BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

(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)

**Experiment Number:** 05117-02  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION|SKIN APPLICATION  
**Species/Strain:** Mouse/CD-1 CRL

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 17:46:43  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 DAYS**

**SURVIVAL SUMMARY STATISTICS**

<b>DOSE</b>	<b>VEHICLE CONTROL</b>	<b>DMBA0.25/ACETONE</b>	<b>DMBA0.25/ TPA 5</b>	<b>DMBA 2.5/ACETONE</b>
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	93.3%	96.7%	73.3%	96.7%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.000N	P=1.000N	P=0.088	P=1.000N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	266.5 (29.5)	200.0 (.)	297.0 (14.9)	193.0 (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	354.7 (4.6)	355.6 (5.4)	343.9 (6.5)	355.4 (5.6)

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**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 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)	66.7%	82.8%	66.7%	96.7%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.027	P=0.420	P=0.025	P=1.000N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	298.1 (13.0)	306.6 (11.9)	277.0 (16.2)	169.0 (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	340.0 (6.9)	344.8 (8.0)	333.0 (9.0)	354.6 (6.4)

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

**Experiment Number:** 05117-02  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION|SKIN APPLICATION  
**Species/Strain:** Mouse/CD-1 CRL

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

**Date Report Requested:** 10/16/2014  
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**Lab:** BAT

**Female MOUSE**  
**FIRST TERMINAL SACRIFICE AT 361 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)	53.3%	100.0%	93.3%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.002	P=0.472N	P=1.000N	P=0.472N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	305.5 (10.6)	. (.)	311.5 (14.5)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	335.1 (7.1)	361.0 (0.0)	357.7 (2.4)	361.0 (0.0)

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

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