Experiment Number: 55801-07 Test Type: ACUTE Route: GAVAGE Species/Strain: Rat/F 344/N

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

C Number:	C55801E
Lock Date:	09/30/2003
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Male
PWG Approval Date	NONE

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Male RAT

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

		Male RAT T TERMINAL SACRIFICE AT 1 DA IVIDUAL SURVIVAL TIMES (DAYS		
DOSE = 0 MG/KG 6 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 0 MG/KG 18 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 0 MG/KG 24 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 0 MG/KG 48 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Male RAT

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

		Male KAT TERMINAL SACRIFICE AT 1 DA IVIDUAL SURVIVAL TIMES (DAYS	-	
DOSE = 50 MG/KG6 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
none				
DOSE = 50 MG/KG18 HR-N TOTAL 6 UNCENSORED DEATH DAYS	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
none CENSORED DEATH DAYS none				
DOSE = 50 MG/KG24 HR-N TOTAL 6 UNCENSORED DEATH DAYS	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
none CENSORED DEATH DAYS none				
DOSE = 50 MG/KG48 HR-N TOTAL 6 UNCENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
CENSORED DEATH DAYS				

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Male RAT

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

		Maie RAI T TERMINAL SACRIFICE AT 1 DA IVIDUAL SURVIVAL TIMES (DAYS		
DOSE = 150MG/KG6HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 150MG/KG18 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 150MG/KG24 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 150MG/KG48 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

	-	Male RAT T TERMINAL SACRIFICE AT 1 DA IVIDUAL SURVIVAL TIMES (DAYS		
DOSE = 1500MG/K6 HR-N				
TOTAL 6	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 1500MG/K18 HR-N				
TOTAL 6	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 1500MG/K24 HR-N				
TOTAL 6	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 1500MG/K48 HR-N				
TOTAL 6	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Male RAT

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

		Male RAI I TERMINAL SACRIFICE AT 1 DA IVIDUAL SURVIVAL TIMES (DAY:		
DOSE = 2000MG/K6 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 2000MG/K18 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 2000MG/K24 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	
DOSE = 2000MG/K48 HR-N TOTAL 6 UNCENSORED DEATH DAYS none CENSORED DEATH DAYS none	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 6	

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

Male RAT
FIRST TERMINAL SACRIFICE AT 1 DAYS

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

DOSE	DSE TIME (DAYS)									
	1(A)	2	3	4	5	6	7	8	9	1(A)
0 MG/KG 6 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0 MG/KG 18 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0 MG/KG 24 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0 MG/KG 48 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 MG/KG6 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 MG/KG18 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 MG/KG24 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 MG/KG48 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150MG/KG6HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150MG/KG18 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150MG/KG24 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
150MG/KG48 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1500MG/K6 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1500MG/K18 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1500MG/K24 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1500MG/K48 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2000MG/K6 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2000MG/K18 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2000MG/K24 HR-N	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2000MG/K48 HR-N	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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

### Male RAT FIRST TERMINAL SACRIFICE AT 1 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	0 MG/KG 6 HR-N	0 MG/KG 18 HR-N	0 MG/KG 24 HR-N	0 MG/KG 48 HR-N
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)				
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				
(STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	1.0	1.0	1.0	1.0
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

#### Male RAT FIRST TERMINAL SACRIFICE AT 1 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	50 MG/KG6 HR-N	50 MG/KG18 HR-N	50 MG/KG24 HR-N	50 MG/KG48 HR-N
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)				
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)		<u>.</u>		
STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	1.0	1.0	1.0	1.0
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

### Male RAT FIRST TERMINAL SACRIFICE AT 1 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	150MG/KG6HR-N	150MG/KG18 HR-N	150MG/KG24 HR-N	150MG/KG48 HR-N
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)				
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				
(STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	1.0	1.0	1.0	1.0
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

### Male RAT FIRST TERMINAL SACRIFICE AT 1 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	1500MG/K6 HR-N	1500MG/K18 HR-N	1500MG/K24 HR-N	1500MG/K48 HR-N
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)				
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				
(STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	1.0	1.0	1.0	1.0
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)

(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

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

### Male RAT FIRST TERMINAL SACRIFICE AT 1 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	2000MG/K6 HR-N	2000MG/K18 HR-N	2000MG/K24 HR-N	2000MG/K48 HR-N
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)				
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				
(STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	1.0	1.0	1.0	1.0
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)

(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

Experiment Number: 55801-07 Test Type: ACUTE Route: GAVAGE Species/Strain: Rat/F 344/N

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Acetaminophen (4-hydroxyacetanilide)

\*\* END OF REPORT \*\*

Date Report Requested: 10/20/2014 Time Report Requested: 15:35:35 First Dose M/F: NA / NA Lab: BAT

(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