

Experiment Number: 55801-06
Test Type: ACUTE
Route: GAVAGE
Species/Strain: Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 09:28:44
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

Experiment Number: 55801-06
 Test Type: ACUTE
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
 Time Report Requested: 09:28:44
 First Dose M/F: NA / NA
 Lab: BAT

| F 344/N Rat MALE | 0 MG/KG 6 HR | 0 MG/KG 18 HR | 0 MG/KG 24 HR | 0 MG/KG 48 HR | 50 MG/KG 6 HR | 50 MG/KG 18 HR |
|--|--------------|---------------|---------------|---------------|---------------|----------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 6 | 6 | 6 | 6 | 6 | 6 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 6 | 6 | 6 | 6 | 6 | 6 |
| Animals Examined Microscopically | 6 | 6 | 6 | 6 | 6 | 6 |
| ALIMENTARY SYSTEM | | | | | | |
| Liver, Left Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Necrosis, Focal | | | | | | |
| Sinusoid, Congestion | | | | | | |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Necrosis | | | 1 [1.0] | | | |
| Necrosis, Focal | | | | | | |
| Sinusoid, Congestion | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |

a - Number of animals examined microscopically at site and number of animals with lesion
 b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06
Test Type: ACUTE
Route: GAVAGE
Species/Strain: Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 09:28:44
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 0 MG/KG 6 HR | 0 MG/KG 18 HR | 0 MG/KG 24 HR | 0 MG/KG 48 HR | 50 MG/KG6 HR | 50 MG/KG18 HR |
|--|--------------|---------------|---------------|---------------|--------------|---------------|
| ENDOCRINE SYSTEM None | | | | | | |
| GENERAL BODY SYSTEM None | | | | | | |
| GENITAL SYSTEM None | | | | | | |
| HEMATOPOIETIC SYSTEM None | | | | | | |
| INTEGUMENTARY SYSTEM None | | | | | | |
| MUSCULOSKELETAL SYSTEM None | | | | | | |
| NERVOUS SYSTEM None | | | | | | |
| RESPIRATORY SYSTEM None | | | | | | |
| SPECIAL SENSES SYSTEM None | | | | | | |
| URINARY SYSTEM Kidney Renal Tubule, Necrosis | (6) | (6) | (6) | (6) | (6) | (6) |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06
 Test Type: ACUTE
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
 Time Report Requested: 09:28:44
 First Dose M/F: NA / NA
 Lab: BAT

| F 344/N Rat MALE | 50 MG/KG24 HR | 50 MG/KG48 HR | 150MG/KG6 HR | 150MG/KG18 HR | 150MG/KG24 HR | 150MG/KG48 HR |
|--|---------------|---------------|--------------|---------------|---------------|---------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 6 | 6 | 6 | 6 | 6 | 6 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 6 | 6 | 6 | 6 | 6 | 6 |
| Animals Examined Microscopically | 6 | 6 | 6 | 6 | 6 | 6 |
| ALIMENTARY SYSTEM | | | | | | |
| Liver, Left Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Necrosis, Focal | | | | | | |
| Sinusoid, Congestion | | | | | | |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Necrosis | | | | | | |
| Necrosis, Focal | | | | | | |
| Sinusoid, Congestion | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06
Test Type: ACUTE
Route: GAVAGE
Species/Strain: Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 09:28:44
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 50 MG/KG24 HR | 50 MG/KG48 HR | 150MG/KG6 HR | 150MG/KG18 HR | 150MG/KG24 HR | 150MG/KG48 HR |
|--|---------------|---------------|--------------|---------------|---------------|---------------|
| ENDOCRINE SYSTEM None | | | | | | |
| GENERAL BODY SYSTEM None | | | | | | |
| GENITAL SYSTEM None | | | | | | |
| HEMATOPOIETIC SYSTEM None | | | | | | |
| INTEGUMENTARY SYSTEM None | | | | | | |
| MUSCULOSKELETAL SYSTEM None | | | | | | |
| NERVOUS SYSTEM None | | | | | | |
| RESPIRATORY SYSTEM None | | | | | | |
| SPECIAL SENSES SYSTEM None | | | | | | |
| URINARY SYSTEM Kidney Renal Tubule, Necrosis | (6) | (6) | (6) | (6) | (6) | (6) |

a - Number of animals examined microscopically at site and number of animals with lesion
b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06
 Test Type: ACUTE
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
 Time Report Requested: 09:28:44
 First Dose M/F: NA / NA
 Lab: BAT

| F 344/N Rat MALE | 1500MG/K6 HR | 1500MG/K18 HR | 1500MG/K24 HR | 1500MG/K48 HR | 2000MG/K6 HR | 2000MG/K18 HR |
|--|--------------|---------------|---------------|---------------|--------------|---------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 6 | 6 | 6 | 6 | 6 | 6 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 6 | 6 | 6 | 6 | 6 | 6 |
| Animals Examined Microscopically | 6 | 6 | 6 | 6 | 6 | 6 |
| ALIMENTARY SYSTEM | | | | | | |
| Liver, Left Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | 4 [1.0] | 6 [1.8] | | |
| Centrilobular, Necrosis | | 3 [1.7] | 5 [2.0] | 6 [1.5] | | 6 [1.8] |
| Hepatocyte, Degeneration | | | | 4 [1.5] | | |
| Hepatocyte, Hypertrophy | | 2 [1.0] | 1 [1.0] | | | 2 [1.5] |
| Hepatocyte, Regeneration | | | | 5 [1.6] | | |
| Necrosis, Focal | 3 [1.0] | | | | 3 [1.0] | |
| Sinusoid, Congestion | | 2 [2.0] | 2 [1.5] | 2 [1.5] | | 4 [2.8] |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | 1 [1.0] | 3 [1.0] | 6 [2.0] | | 1 [1.0] |
| Centrilobular, Necrosis | | 5 [1.6] | 5 [2.0] | 6 [2.2] | | 5 [3.0] |
| Hepatocyte, Degeneration | | | | 5 [1.8] | | |
| Hepatocyte, Hypertrophy | | 1 [1.0] | | | | 1 [1.0] |
| Hepatocyte, Regeneration | | | | 5 [1.8] | | |
| Necrosis | | | | | | |
| Necrosis, Focal | 3 [1.0] | | | | 3 [1.0] | |
| Sinusoid, Congestion | | 3 [2.3] | 3 [1.7] | 5 [2.2] | | 3 [2.3] |

CARDIOVASCULAR SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06
Test Type: ACUTE
Route: GAVAGE
Species/Strain: Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 09:28:44
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 1500MG/K6 HR | 1500MG/K18 HR | 1500MG/K24 HR | 1500MG/K48 HR | 2000MG/K6 HR | 2000MG/K18 HR |
|------------------------|--------------|---------------|---------------|---------------|--------------|---------------|
| ENDOCRINE SYSTEM | | | | | | |
| None | | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| None | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| None | | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (6) | (6) | (6) | (6) | (6) | (6) |
| Renal Tubule, Necrosis | | | | 1 [2.0] | | |

a - Number of animals examined microscopically at site and number of animals with lesion
b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06

Test Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014

Time Report Requested: 09:28:45

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 2000MG/K24 HR | 2000MG/K48 HR | 0 MG/KG SPECIAL | 50 MG/KGSPECIAL | 1500MG/KSPECIAL |
|---|---------------|---------------|-----------------|-----------------|-----------------|
| Disposition Summary | | | | | |
| Animals Initially In Study | 6 | 6 | 6 | 6 | 6 |
| Early Deaths | | | | | |
| Survivors | | | | | |
| Terminal Sacrifice | 6 | 6 | | | |
| Animals Examined Microscopically | 6 | 6 | | | |
| ALIMENTARY SYSTEM | | | | | |
| Liver, Left Lobe | (6) | (6) | (0) | (0) | (0) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | 1 [1.0] | 6 [1.8] | | | |
| Centrilobular, Necrosis | 5 [2.4] | 6 [2.0] | | | |
| Hepatocyte, Degeneration | | 3 [1.3] | | | |
| Hepatocyte, Hypertrophy | 4 [1.0] | | | | |
| Hepatocyte, Regeneration | | 6 [2.2] | | | |
| Necrosis, Focal | | | | | |
| Sinusoid, Congestion | 2 [1.5] | 3 [1.3] | | | |
| Liver, Median Lobe | (6) | (6) | (0) | (0) | (0) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | 2 [1.5] | 6 [1.8] | | | |
| Centrilobular, Necrosis | 6 [2.7] | 6 [2.5] | | | |
| Hepatocyte, Degeneration | | 3 [1.0] | | | |
| Hepatocyte, Hypertrophy | 1 [1.0] | | | | |
| Hepatocyte, Regeneration | | 6 [2.3] | | | |
| Necrosis | | | | | |
| Necrosis, Focal | | | | | |
| Sinusoid, Congestion | 4 [3.0] | 3 [2.3] | | | |
| CARDIOVASCULAR SYSTEM | | | | | |
| None | | | | | |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 55801-06

Test Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014

Time Report Requested: 09:28:45

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 2000MG/K24 HR | 2000MG/K48 HR | 0 MG/KG SPECIAL | 50 MG/KGSPECIAL | 1500MG/KSPECIAL |
|------------------------|---------------|---------------|-----------------|-----------------|-----------------|
| ENDOCRINE SYSTEM | | | | | |
| None | | | | | |
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| None | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | |
| None | | | | | |
| INTEGUMENTARY SYSTEM | | | | | |
| None | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |
| NERVOUS SYSTEM | | | | | |
| None | | | | | |
| RESPIRATORY SYSTEM | | | | | |
| None | | | | | |
| SPECIAL SENSES SYSTEM | | | | | |
| None | | | | | |
| URINARY SYSTEM | | | | | |
| Kidney | (6) | (6) | (0) | (0) | (0) |
| Renal Tubule, Necrosis | 1 [1.0] | | | | |

**** END OF REPORT ****

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)