

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 15:36:14
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 |

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Route: GAVAGE
Species/Strain: Rat/F 344/N

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

| F 344/N Rat MALE | 0 MG/KG 6 HR-N | 0 MG/KG 18 HR-N | 0 MG/KG 24 HR-N | 0 MG/KG 48 HR-N | 50 MG/KG6 HR-N | 50 MG/KG18 HR-N |
|---|----------------|-----------------|-----------------|-----------------|----------------|-----------------|
| 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 | | | | | | |
| Sinusoid, Congestion | | | | | | |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Sinusoid, Congestion | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (0) | (0) | (0) | (0) | (0) | (0) |
| GENERAL BODY SYSTEM | | | | | | |

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

Experiment Number: 55801-07

Test Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014

Time Report Requested: 15:36:14

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 0 MG/KG 6 HR-N | 0 MG/KG 18 HR-N | 0 MG/KG 24 HR-N | 0 MG/KG 48 HR-N | 50 MG/KG6 HR-N | 50 MG/KG18 HR-N |
|------------------------|----------------|-----------------|-----------------|-----------------|----------------|-----------------|
| 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 | | | | | | |

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
 Time Report Requested: 15:36:14
 First Dose M/F: NA / NA
 Lab: BAT

| F 344/N Rat MALE | 50 MG/KG24 HR-N | 50 MG/KG48 HR-N | 150MG/KG6HR-N | 150MG/KG18 HR-N | 150MG/KG24 HR-N | 150MG/KG48 HR-N |
|---|-----------------|-----------------|---------------|-----------------|-----------------|-----------------|
| 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 | | | | | | |
| Sinusoid, Congestion | | | | | | |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | | | |
| Centrilobular, Necrosis | | | | | | |
| Hepatocyte, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | |
| Hepatocyte, Regeneration | | | | | | |
| Sinusoid, Congestion | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (0) | (0) | (0) | (0) | (0) | (0) |
| GENERAL BODY SYSTEM | | | | | | |

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

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

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Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
Time Report Requested: 15:36:14
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 50 MG/KG24 HR-N | 50 MG/KG48 HR-N | 150MG/KG6HR-N | 150MG/KG18 HR-N | 150MG/KG24 HR-N | 150MG/KG48 HR-N |
|------------------------|-----------------|-----------------|---------------|-----------------|-----------------|-----------------|
| 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 | | | | | | |

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

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

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014
 Time Report Requested: 15:36:14
 First Dose M/F: NA / NA
 Lab: BAT

| F 344/N Rat MALE | 1500MG/K6 HR-N | 1500MG/K18 HR-N | 1500MG/K24 HR-N | 1500MG/K48 HR-N | 2000MG/K6 HR-N | 2000MG/K18 HR-N |
|---|----------------|-----------------|-----------------|-----------------|----------------|-----------------|
| 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 | | | | 5 (83%) | 1 (17%) | |
| Centrilobular, Necrosis | 1 (17%) | 4 (67%) | 6 (100%) | 6 (100%) | 2 (33%) | 4 (67%) |
| Hepatocyte, Degeneration | | 1 (17%) | | 2 (33%) | | 2 (33%) |
| Hepatocyte, Hypertrophy | | | 3 (50%) | | | 2 (33%) |
| Hepatocyte, Regeneration | | | | 4 (67%) | | |
| Sinusoid, Congestion | | 2 (33%) | 6 (100%) | 3 (50%) | | 4 (67%) |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | | | | 5 (83%) | | |
| Centrilobular, Necrosis | 2 (33%) | 4 (67%) | 6 (100%) | 6 (100%) | 3 (50%) | 4 (67%) |
| Hepatocyte, Degeneration | | 1 (17%) | | 2 (33%) | | 2 (33%) |
| Hepatocyte, Hypertrophy | | | 3 (50%) | | | 1 (17%) |
| Hepatocyte, Regeneration | | | | 3 (50%) | | |
| Sinusoid, Congestion | | 3 (50%) | 6 (100%) | 5 (83%) | | 4 (67%) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (0) | (0) | (0) | (0) | (0) | (0) |
| GENERAL BODY SYSTEM | | | | | | |

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

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Species/Strain: Rat/F 344/N

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

| F 344/N Rat MALE | 1500MG/K6 HR-N | 1500MG/K18 HR-N | 1500MG/K24 HR-N | 1500MG/K48 HR-N | 2000MG/K6 HR-N | 2000MG/K18 HR-N |
|------------------------|----------------|-----------------|-----------------|-----------------|----------------|-----------------|
| 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 (17%) | 2 (33%) | | |

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

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Route: GAVAGE

Species/Strain: Rat/F 344/N

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First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 2000MG/K24 HR-N | 2000MG/K48 HR-N |
|----------------------------------|-----------------|-----------------|
| Disposition Summary | | |
| Animals Initially In Study | 6 | 6 |
| Early Deaths | | |
| Survivors | | |
| Terminal Sacrifice | 6 | 6 |
| Animals Examined Microscopically | 6 | 6 |

ALIMENTARY SYSTEM

| | | |
|---|----------|----------|
| Liver, Left Lobe | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | 1 (17%) | 6 (100%) |
| Centrilobular, Necrosis | 6 (100%) | 6 (100%) |
| Hepatocyte, Degeneration | | 3 (50%) |
| Hepatocyte, Hypertrophy | 5 (83%) | |
| Hepatocyte, Regeneration | | 3 (50%) |
| Sinusoid, Congestion | 5 (83%) | 4 (67%) |
| Liver, Median Lobe | (6) | (6) |
| Centrilobular, Infiltration Cellular, Mononuclear Cl | 1 (17%) | 6 (100%) |
| Centrilobular, Necrosis | 5 (83%) | 6 (100%) |
| Hepatocyte, Degeneration | | 3 (50%) |
| Hepatocyte, Hypertrophy | 5 (83%) | |
| Hepatocyte, Regeneration | | 4 (67%) |
| Sinusoid, Congestion | 5 (83%) | 4 (67%) |

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

| | | |
|----------------|-----|-----|
| Adrenal Cortex | (0) | (1) |
|----------------|-----|-----|

GENERAL BODY SYSTEM

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

Experiment Number: 55801-07

Test Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

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Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014

Time Report Requested: 15:36:15

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 2000MG/K24 HR-N | 2000MG/K48 HR-N |
|-------------------------|------------------------|------------------------|
| 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) |
| Renal Tubule, Necrosis | 5 (83%) | 1 (17%) |

**** END OF REPORT ****

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