Experiment Number: 55801-06 P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) Test Type: ACUTE

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Date Report Requested: 10/20/2014 Time Report Requested: 09:29:06

First Dose M/F: NA / NA

Lab: BAT

C Number: C55801E

Lock Date: 09/30/2003

Cage Range: ΑII

Route: GAVAGE

Species/Strain: Rat/F 344/N

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Male

PWG Approval Date NONE

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:06

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
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						

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

Necrosis

Necrosis, Focal Sinusoid, Congestion 1 (17%)

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

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:07

First Dose M/F: NA / NA

Lab: BAT

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

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:07

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						

ENDOCRINE SYSTEM

None

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

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:07

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
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)

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: 09:29:07

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

F 344/N Rat MALE	1500MG/K6 HR	1500MG/K18 HR	1500MG/K24 HR	1500MG/K48 HR	2000MG/K6 HR	2000MG/K18 H
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 (67%)	6 (100%)		
Centrilobular, Necrosis		3 (50%)	5 (83%)	6 (100%)		6 (100%)
Hepatocyte, Degeneration				4 (67%)		
Hepatocyte, Hypertrophy		2 (33%)	1 (17%)			2 (33%)
Hepatocyte, Regeneration				5 (83%)		
Necrosis, Focal	3 (50%)				3 (50%)	
Sinusoid, Congestion		2 (33%)	2 (33%)	2 (33%)		4 (67%)
Liver, Median Lobe	(6)	(6)	(6)	(6)	(6)	(6)
Centrilobular, Infiltration Cellular, Mononuclear Cl		1 (17%)	3 (50%)	6 (100%)		1 (17%)
Centrilobular, Necrosis		5 (83%)	5 (83%)	6 (100%)		5 (83%)
Hepatocyte, Degeneration				5 (83%)		
Hepatocyte, Hypertrophy		1 (17%)				1 (17%)
Hepatocyte, Regeneration				5 (83%)		
Necrosis						
Necrosis, Focal	3 (50%)				3 (50%)	
Sinusoid, Congestion		3 (50%)	3 (50%)	5 (83%)		3 (50%)

ENDOCRINE SYSTEM

None

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

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:07

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
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) 1 (17%)	(6)	(6)

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: 09:29:07

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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 (17%)	6 (100%)			
Centrilobular, Necrosis	5 (83%)	6 (100%)			
Hepatocyte, Degeneration		3 (50%)			
Hepatocyte, Hypertrophy	4 (67%)				
Hepatocyte, Regeneration		6 (100%)			
Necrosis, Focal					
Sinusoid, Congestion	2 (33%)	3 (50%)			
Liver, Median Lobe	(6)	(6)	(0)	(0)	(0)
Centrilobular, Infiltration Cellular, Mononuclear Cl	2 (33%)	6 (100%)			
Centrilobular, Necrosis	6 (100%)	6 (100%)			
Hepatocyte, Degeneration		3 (50%)			
Hepatocyte, Hypertrophy	1 (17%)				
Hepatocyte, Regeneration		6 (100%)			
Necrosis					
Necrosis, Focal					
Sinusoid, Congestion	4 (67%)	3 (50%)			

ENDOCRINE SYSTEM

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

Renal Tubule, Necrosis

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

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: 09:29:07

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
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)

** END OF REPORT **

1 (17%)

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