Experiment Number: 55801-07 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] Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Time Report Requested: 15:35:54 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 Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/20/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 15:35:54

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Time Report Requested: 10/20/201 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 Early Deaths	6	6	6	6	6	6
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	at Type: ACUTE AVERAGE SEVERITY GRADES[b] ute: GAVAGE Test Compound: Acetaminophen (4-hydroxyacetanilide)				H Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54 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							
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

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] Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Time Report Requested: 10/20/2017 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	AVERAGE SEV	NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH /ERAGE SEVERITY GRADES[b] pound: Acetaminophen (4-hydroxyacetanilide)			H Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54 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						
INTEGUMENTARY SYSTEM None						
MUSCULOSKELETAL SYSTEM <u>None</u>						
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

Test Type: ACUTE

Route: GAVAGE

Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/20/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 15:35:54

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Time Report Requested: 10/20/201 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 [2.0]	1 [1.0]	
Centrilobular, Necrosis	1 [1.0]	4 [1.8]	6 [2.7]	6 [2.2]	2 [1.0]	4 [1.8]
Hepatocyte, Degeneration		1 [1.0]		2 [1.0]		2 [1.0]
Hepatocyte, Hypertrophy			3 [1.3]			2 [1.0]
Hepatocyte, Regeneration				4 [2.0]		
Sinusoid, Congestion		2 [2.5]	6 [2.7]	3 [1.7]		4 [2.3]
Liver, Median Lobe	(6)	(6)	(6)	(6)	(6)	(6)
Centrilobular, Infiltration Cellular, Mononuclear Cl				5 [1.2]		
Centrilobular, Necrosis	2 [1.0]	4 [2.0]	6 [2.8]	6 [2.2]	3 [1.0]	4 [2.3]
Hepatocyte, Degeneration		1 [1.0]		2 [1.0]		2 [1.0]
Hepatocyte, Hypertrophy			3 [1.3]			1 [1.0]
Hepatocyte, Regeneration				3 [2.0]		
Sinusoid, Congestion		3 [2.3]	6 [2.8]	5 [1.6]		4 [2.8]
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	Test Compound: Acetaminophen (4-hydroxyacetanilide)				Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54 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							
INTEGUMENTARY SYSTEM None							
MUSCULOSKELETAL SYSTEM None							
NERVOUS SYSTEM None							
RESPIRATORY SYSTEM							
SPECIAL SENSES SYSTEM None							
URINARY SYSTEM Kidney Renal Tubule, Necrosis	(6)	(6)	(6) 1 [2.0]	(6) 2 [1.0]	(6)	(6)	

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

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] Date Report Requested: 10/20/2014 Time Report Requested: 15:35:54

Test Compound: Acetaminophen (4-hydroxyacetanilide)

Time Report Requested: 15:35:54 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 Early Deaths	6	6
Survivors		
Terminal Sacrifice	6	6
Animals Examined Microscopically	6	6
ALIMENTARY SYSTEM		
Liver, Left Lobe	(6)	(6)
Centrilobular, Infiltration Cellular, Mononuclear Cl	1 [1.0]	6 [1.3]
Centrilobular, Necrosis	6 [2.0]	6 [2.3]
Hepatocyte, Degeneration		3 [1.7]
Hepatocyte, Hypertrophy	5 [1.6]	
Hepatocyte, Regeneration		3 [1.7]
Sinusoid, Congestion	5 [1.8]	4 [2.3]
Liver, Median Lobe	(6)	(6)
Centrilobular, Infiltration Cellular, Mononuclear Cl	1 [1.0]	6 [1.3]
Centrilobular, Necrosis	5 [2.8]	6 [2.3]
Hepatocyte, Degeneration		3 [1.7]
Hepatocyte, Hypertrophy	5 [1.6]	
Hepatocyte, Regeneration		4 [1.5]
Sinusoid, Congestion	5 [2.2]	4 [1.8]
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		B: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH I AVERAGE SEVERITY GRADES[b] Test Compound: Acetaminophen (4-hydroxyacetanilide)				
F 344/N Rat MALE	2000MG/K24 HR-N	2000MG/K48 HR-N	-			
None			-			
NITAL SYSTEM			-			
EMATOPOIETIC SYSTEM None			-			
TEGUMENTARY SYSTEM None			_			
USCULOSKELETAL SYSTEM None			_			
ERVOUS SYSTEM None			_			
ESPIRATORY SYSTEM None			_			
PECIAL SENSES SYSTEM None			_			
IRINARY SYSTEM						
Kidney Renal Tubule, Necrosis	(6) 5 [1.6]	(6) 1 [1.0]	_			

** END OF REPORT **

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