Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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:

Removal Date Range: All

Treatment Groups: All

Study Gender: Male

PWG Approval Date NONE

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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) |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| None | | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| None | | | | | | |
| INTEGUMENTARY SYSTEM | , | , | | | | |
| None | | | | | | |
| | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

First Dose M/F: NA / NA

| 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 |
|----------------------------|--------------|---------------|---------------|---------------|--------------|---------------|
| None | | | | | | |
| RESPIRATORY SYSTEM None | | | | | | |
| SPECIAL SENSES SYSTEM None | | | | | | |
| URINARY SYSTEM Kidney | (6) | (6) | (6) | (6) | (6) | (6) |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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) |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| CARDIOVASCULAR SYSTEM None | | | | | | |
| | | | | | | |
| ENDOCRINE SYSTEM None | | | | | , | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| None | | | , | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

First Dose M/F: NA / NA

| 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 | | | | | | |
| RESPIRATORY SYSTEM None | | | | | | |
| SPECIAL SENSES SYSTEM None | | | | | | |
| URINARY SYSTEM Kidney | (6) | (6) | (6) | (6) | (6) | (6) |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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) |
| Liver, Median Lobe | (6) | (6) | (6) | (6) | (6) | (6) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| None | | | | | | |
| | | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| None | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

First Dose M/F: NA / NA

| F 344/N Rat MALE | 1500MG/K6 HR | 1500MG/K18 HR | 1500MG/K24 HR | 1500MG/K48 HR | 2000MG/K6 HR | 2000MG/K18 HR |
|----------------------------|--------------|---------------|---------------|---------------|--------------|---------------|
| None | | | | | | |
| RESPIRATORY SYSTEM None | | | | | | |
| SPECIAL SENSES SYSTEM None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (6) | (6) | (6) | (6) | (6) | (6) |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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) |
| Liver, Median Lobe | (6) | (6) | (0) | (0) | (0) |
| CARDIOVASCULAR SYSTEM | | | | | |
| None | | | | | |
| | | | | | |
| ENDOCRINE SYSTEM | | | | | |
| None | | | | | |
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| None | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | |
| None | | | | | |
| NOTIC | | | | | |
| INTEGUMENTARY SYSTEM | | | | | |
| None | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

First Dose M/F: NA / NA

Test Compound: Acetaminophen (4-hydroxyacetanilide)

| F 344 | I/N Rat MALE | 2000MG/K24 HR | 2000MG/K48 HR | 0 MG/KG SPECIAL | 50 MG/KGSPECIAL | 1500MG/KSPECIAL |
|-----------------|--------------|---------------|---------------|-----------------|-----------------|-----------------|
| None | | | | | | |
| RESPIRATORY SYS | STEM | | | | | |
| SPECIAL SENSES | SYSTEM | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | | (6) | (6) | (0) | (0) | (0) |

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Benign or Malignant

Total Uncertain Neoplasms

Test Type: ACUTE

Route: GAVAGE

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 **Tumor Summary for MALE Total Animals with Primary Neoplasms (b) Total Primary Neoplasms Total Animals with Benign Neoplasms Total Benign Neoplasms Total Animals with Malignant Neoplasms Total Malignant Neoplasms Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms Total Animals with Malignant Neoplasms Uncertain Primary Site Total Animals with Neoplasms Uncertain -**

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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

Tumor Summary for MALE

Species/Strain: Rat/F 344/N

Total Animals with Primary Neoplasms (b)
Total Primary Neoplasms

Total Animals with Benign Neoplasms
Total Benign Neoplasms

Total Animals with Malignant Neoplasms
Total Malignant Neoplasms

Total Animals with Metastatic Neoplasms

Total Metastatic Neoplasms

Total Animals with Malignant Neoplasms Uncertain Primary Site

Total Animals with Neoplasms Uncertain - Benign or Malignant

Total Uncertain Neoplasms

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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

Tumor Summary for MALE

Species/Strain: Rat/F 344/N

Total Animals with Primary Neoplasms (b)
Total Primary Neoplasms

Total Animals with Benign Neoplasms
Total Benign Neoplasms

Total Animals with Malignant Neoplasms
Total Malignant Neoplasms

Total Animals with Metastatic Neoplasms

Total Metastatic Neoplasms

Total Animals with Malignant Neoplasms Uncertain Primary Site

Total Animals with Neoplasms Uncertain - Benign or Malignant

Total Uncertain Neoplasms

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically

Species/Strain: Rat/F 344/N

Test Type: ACUTE

Route: GAVAGE

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Test Compound: Acetaminophen (4-hydroxyacetanilide)

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

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 **Tumor Summary for MALE Total Animals with Primary Neoplasms (b) Total Primary Neoplasms Total Animals with Benign Neoplasms Total Benign Neoplasms Total Animals with Malignant Neoplasms Total Malignant Neoplasms Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms Total Animals with Malignant Neoplasms Uncertain Primary Site**

** END OF REPORT **

Total Animals with Neoplasms Uncertain -

Total Uncertain Neoplasms

Benign or Malignant

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

b - Primary tumors: all tumors except metastatic tumors

^{*} Number of animals with any tissue examined microscopically