

TDMS No. 55801 - 06
Test Type: ACUTE
Route: GAVAGE
Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
ACETAMINOPHEN (4-HYDROXYACETANILIDE)
CAS Number: 103-90-2

Date Report Reqsted: 01/10/2007
Time Report Reqsted: 12:43:35
First Dose M/F: 12/16/02 / 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: Include 002 0 MG/KG 18 HR Include 006 50 MG/KG18 HR Include 010 150MG/KG18 HR
Include 014 1500MG/K18 HR Include 018 2000MG/K18 HR

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| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 MG/KG 18 HR | 1 | 1 | 1 | 1 | 1 | 1 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | |
|--------------------|---|---|---|---|---|---|----------|
| Liver, Left Lobe | + | + | + | + | + | + | 6 |
| Liver, Median Lobe | + | + | + | + | + | + | 6 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 2

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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| | | | | | | |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 MG/KG 18 HR | 1 | 1 | 1 | 1 | 1 | 1 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

NONE

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

Kidney

+ + + + + +

6

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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 Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 50 MG/KG18 HR | 2 | 2 | 2 | 2 | 2 | 2 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | |
|--------------------|---|---|---|---|---|---|----------|
| Liver, Left Lobe | + | + | + | + | + | + | 6 |
| Liver, Median Lobe | + | + | + | + | + | + | 6 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

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1-4 .. Lesion qualified as:

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| | | | | | | |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 50 MG/KG18 HR | 2 | 2 | 2 | 2 | 2 | 2 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

NONE

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

Kidney

+ + + + + +

6

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

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M .. Missing tissue

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 Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 150MG/KG18 HR | 3 | 3 | 3 | 3 | 3 | 3 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | |
|--------------------|---|---|---|---|---|---|----------|
| Liver, Left Lobe | + | + | + | + | + | + | 6 |
| Liver, Median Lobe | + | + | + | + | + | + | 6 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

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 Lab: BAT

| | | | | | | |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 150MG/KG18 HR | 3 | 3 | 3 | 3 | 3 | 3 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

NONE

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

Kidney

.....
 + + + + + +

6

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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 Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 1500MG/K18 HR | 4 | 4 | 4 | 4 | 4 | 4 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|-------|
| Liver, Left Lobe | + | + | + | + | + | + | 6 | |
| Centrilobular, Necrosis | | 1 | | | 1 | 3 | | 3 1.7 |
| Hepatocyte, Hypertrophy | 1 | | | | | 1 | | 2 1.0 |
| Sinusoid, Congestion | | 1 | | | | 3 | | 2 2.0 |
| | | | | | | | | |
| Liver, Median Lobe | + | + | + | + | + | + | 6 | |
| Centrilobular, Infiltration Cellular, Mononuclear Cell | | | | 1 | | | | 1 1.0 |
| Centrilobular, Necrosis | 2 | 1 | | 1 | 1 | 3 | | 5 1.6 |
| Hepatocyte, Hypertrophy | | | | | | 1 | | 1 1.0 |
| Sinusoid, Congestion | 3 | | 1 | | | 3 | | 3 2.3 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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| | | | | | | |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 1500MG/K18 HR | 4 | 4 | 4 | 4 | 4 | 4 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

HEMATOPOIETIC SYSTEM
 NONE

INTEGUMENTARY SYSTEM
 NONE

MUSCULOSKELETAL SYSTEM
 NONE

NERVOUS SYSTEM
 NONE

RESPIRATORY SYSTEM
 NONE

SPECIAL SENSES SYSTEM
 NONE

URINARY SYSTEM

| | | | | | | | |
|--------|---|---|---|---|---|---|----------|
| Kidney | + | + | + | + | + | + | 6 |
|--------|---|---|---|---|---|---|----------|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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 First Dose M/F: 12/16/02 / NA
 Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 2000MG/K18 HR | 5 | 5 | 5 | 5 | 5 | 5 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|--------------|
| Liver, Left Lobe | + | + | + | + | + | + | 6 | |
| Centrilobular, Necrosis | 2 | 1 | 3 | 3 | 1 | 1 | | 6 1.8 |
| Hepatocyte, Hypertrophy | | 2 | 1 | | | | | 2 1.5 |
| Sinusoid, Congestion | 3 | | 3 | 3 | 2 | | | 4 2.8 |
| | | | | | | | | |
| Liver, Median Lobe | + | + | + | + | + | + | 6 | |
| Centrilobular, Infiltration Cellular, Mononuclear Cell | | | | | | 1 | | 1 1.0 |
| Centrilobular, Necrosis | 2 | 4 | 3 | 3 | 3 | | | 5 3.0 |
| Hepatocyte, Hypertrophy | | 1 | | | | | | 1 1.0 |
| Sinusoid, Congestion | 3 | | 3 | 1 | | | | 3 2.3 |

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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x .. Lesion present

I .. Insufficient tissue

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1-4 .. Lesion qualified as:

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 Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | |
| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 2000MG/K18 HR | 5 | 5 | 5 | 5 | 5 | 5 |
| | 0 | 0 | 0 | 1 | 1 | 1 |
| | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | * TOTALS |

HEMATOPOIETIC SYSTEM
 NONE

INTEGUMENTARY SYSTEM
 NONE

MUSCULOSKELETAL SYSTEM
 NONE

NERVOUS SYSTEM
 NONE

RESPIRATORY SYSTEM
 NONE

SPECIAL SENSES SYSTEM
 NONE

URINARY SYSTEM

| | | | | | | | |
|--------|---|---|---|---|---|---|----------|
| Kidney | + | + | + | + | + | + | 6 |
|--------|---|---|---|---|---|---|----------|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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 Lab: BAT

| | | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|-----------|---|---|---|---|---|-----------------|
| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | | | | | |
| FISCHER 344 RATS MALE | | 0 | 0 | 0 | 0 | 0 | 0 |
| | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 |
| 2000MG/K18 HR | | 5 | 5 | 5 | 5 | 5 | 5 |
| | | 0 | 0 | 0 | 1 | 1 | 1 |
| | | 4 | 5 | 6 | 6 | 7 | 8 |
| | | | | | | | * TOTALS |

*** END OF MALE DATA ***

*** END OF REPORT ***

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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