

Experiment Number: 20107-01
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Test Compound: N,N-Dimethyl-p-toluidine
CAS Number: 99-97-8

Date Report Requested: 10/22/2014
Time Report Requested: 11:57:45
First Dose M/F: NA / NA
Lab: BAT

| | |
|-----------------------------|------------|
| C Number: | C20107 |
| Lock Date: | 07/14/2004 |
| Cage Range: | All |
| Date Range: | All |
| Reasons For Removal: | All |
| Removal Date Range: | All |
| Treatment Groups: | All |
| Study Gender: | Both |
| PWG Approval Date | NONE |

Experiment Number: 20107-01

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First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

CAS Number: 99-97-8

Lab: BAT

| F 344/N Rat MALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|----------------------------------|------|-------|------|-------|------|-------|------|-------|------|-------|------|-------|
| Disposition Summary | | | | | | | | | | | | |
| Animals Initially In Study | 10 | | 10 | | 10 | | 10 | | 10 | | 10 | |
| Early Deaths | | | | | | | | | | | | |
| Moribund Sacrifice | | | | | | | | | 1 | | 1 | |
| Natural Death | | | | | | | | | | | 9 | |
| Survivors | | | | | | | | | | | | |
| Terminal Sacrifice | 10 | | 10 | | 10 | | 10 | | 9 | | | |
| Animals Examined Microscopically | 10 | | 10 | | 10 | | 10 | | 10 | | 10 | |
| ALIMENTARY SYSTEM | | | | | | | | | | | | |
| Esophagus | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Cecum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Colon | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Rectum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Duodenum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Ileum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Jejunum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Liver | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Pancreas | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Salivary Glands | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Stomach, Forestomach | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Stomach, Glandular | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| CARDIOVASCULAR SYSTEM | | | | | | | | | | | | |
| Blood Vessel | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Heart | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| ENDOCRINE SYSTEM | | | | | | | | | | | | |
| Adrenal Cortex | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |

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

Experiment Number: 20107-01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/22/2014

Time Report Requested: 11:57:45

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|------------------------|------|-------|------|-------|------|-------|------|-------|------|-------|------|-------|
| Adrenal Medulla | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Islets, Pancreatic | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Parathyroid Gland | (9) | | (0) | | (0) | | (0) | | (8) | | (7) | |
| Pituitary Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (9) | |
| Thyroid Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| GENERAL BODY SYSTEM | | | | | | | | | | | | |
| None | | | | | | | | | | | | |
| GENITAL SYSTEM | | | | | | | | | | | | |
| Epididymis | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Preputial Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Prostate | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Seminal Vesicle | (10) | | (0) | | (0) | | (0) | | (10) | | (8) | |
| Testes | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| HEMATOPOIETIC SYSTEM | | | | | | | | | | | | |
| Bone Marrow | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Lymph Node | (1) | | (0) | | (0) | | (0) | | (1) | | (0) | |
| Lymph Node, Mesenteric | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Spleen | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Thymus | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | |
| Mammary Gland | (10) | | (0) | | (0) | | (0) | | (5) | | (10) | |
| Skin | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | |
| Bone | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| NERVOUS SYSTEM | | | | | | | | | | | | |
| Brain | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |

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

Experiment Number: 20107-01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/22/2014

Time Report Requested: 11:57:45

First Dose M/F: NA / NA

Lab: BAT

| F 344/N Rat MALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|------------------------------|----------|--------------|-------------|--------------|------------|--------------|------------|--------------|------------|--------------|-------------|--------------|
| RESPIRATORY SYSTEM | | | | | | | | | | | | |
| Lung | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Nose | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Trachea | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | |
| Eye | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Harderian Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| URINARY SYSTEM | | | | | | | | | | | | |
| Kidney | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Urinary Bladder | (10) | | (0) | | (0) | | (0) | | (10) | | (9) | |

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

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Species/Strain: Rat/F 344/N

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)
Test Compound: N,N-Dimethyl-p-toluidine
CAS Number: 99-97-8

Date Report Requested: 10/22/2014
Time Report Requested: 11:57:45
First Dose M/F: NA / NA
Lab: BAT

F 344/N Rat MALE

0 MG/KG

62.5 MG/KG

125 MG/KG

250 MG/KG

500 MG/KG

1000 MG/KG

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 -
Benign or Malignant**

Total Uncertain Neoplasms

END OF MALE DATA

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

Experiment Number: 20107-01

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

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CAS Number: 99-97-8

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: BAT

| F 344/N Rat FEMALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|----------------------------------|------|-------|------|-------|------|-------|------|-------|------|-------|------|-------|
| Disposition Summary | | | | | | | | | | | | |
| Animals Initially In Study | 10 | | 10 | | 10 | | 10 | | 10 | | 10 | |
| Early Deaths | | | | | | | | | | | | |
| Moribund Sacrifice | | | | | | | | | | | 10 | |
| Survivors | | | | | | | | | | | | |
| Terminal Sacrifice | 10 | | 10 | | 10 | | 10 | | 10 | | | |
| Animals Examined Microscopically | 10 | | 10 | | 10 | | 10 | | 10 | | 10 | |
| ALIMENTARY SYSTEM | | | | | | | | | | | | |
| Esophagus | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Cecum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Colon | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Large, Rectum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Duodenum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Ileum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Intestine Small, Jejunum | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Liver | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Pancreas | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Salivary Glands | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Stomach, Forestomach | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Stomach, Glandular | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| CARDIOVASCULAR SYSTEM | | | | | | | | | | | | |
| Blood Vessel | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Heart | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| ENDOCRINE SYSTEM | | | | | | | | | | | | |
| Adrenal Cortex | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Adrenal Medulla | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |

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

b - Primary tumors: all tumors except metastatic tumors

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Lab: BAT

| F 344/N Rat FEMALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|------------------------|------|-------|------|-------|------|-------|------|-------|------|-------|------|-------|
| Islets, Pancreatic | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Parathyroid Gland | (9) | | (0) | | (0) | | (0) | | (9) | | (8) | |
| Pituitary Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Thyroid Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| GENERAL BODY SYSTEM | | | | | | | | | | | | |
| None | | | | | | | | | | | | |
| GENITAL SYSTEM | | | | | | | | | | | | |
| Clitoral Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Ovary | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Uterus | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| HEMATOPOIETIC SYSTEM | | | | | | | | | | | | |
| Bone Marrow | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Lymph Node, Mesenteric | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Spleen | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Thymus | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | |
| Mammary Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Skin | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | |
| Bone | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| NERVOUS SYSTEM | | | | | | | | | | | | |
| Brain | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | |
| Lung | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Nose | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |

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

Experiment Number: 20107-01

Test Type: 90-DAY

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Species/Strain: Rat/F 344/N

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Lab: BAT

| F 344/N Rat FEMALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|------------------------------|----------|--------------|-------------|--------------|------------|--------------|------------|--------------|------------|--------------|-------------|--------------|
| Trachea | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | |
| Eye | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Harderian Gland | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |
| Lacrimal Gland | (1) | | (0) | | (0) | | (0) | | (0) | | (0) | |
| URINARY SYSTEM | | | | | | | | | | | | |
| Kidney | (10) | | (10) | | (10) | | (10) | | (10) | | (10) | |
| Urinary Bladder | (10) | | (0) | | (0) | | (0) | | (10) | | (10) | |

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

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| F 344/N Rat FEMALE | 0 | MG/KG | 62.5 | MG/KG | 125 | MG/KG | 250 | MG/KG | 500 | MG/KG | 1000 | MG/KG |
|--------------------|---|-------|------|-------|-----|-------|-----|-------|-----|-------|------|-------|
|--------------------|---|-------|------|-------|-----|-------|-----|-------|-----|-------|------|-------|

Tumor Summary for FEMALE

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

**** END OF REPORT ****

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