

TDMs No. 20006 - 02

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]**

Date Report Reqsted: 06/05/2007

Test Type: 90-DAY

INDOLE-3-CARBINOL

Time Report Reqsted: 07:56:47

Route: GAVAGE

CAS Number: 700-06-1

First Dose M/F: 09/01/04 / 09/02/04

Species/Strain: MICE/B6C3F1

Lab: SRI

F1_M3

C Number: C20006
Lock Date: 03/07/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
TDMSE Version: 1.7.0

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Lab: SRI

| B6C3F1 MICE MALE | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG |
|--|---------|------------|-------------|------------|-----------|
| Disposition Summary | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | |
| Survivors | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic | 3 [1.0] | | | | |
| Liver | (10) | (10) | (10) | (10) | (10) |
| Centrilobular, Vacuolization Cytoplasmic | | | | | 1 [3.0] |
| CARDIOVASCULAR SYSTEM | | | | | |
| None | | | | | |
| ENDOCRINE SYSTEM | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) |
| Accessory Adrenal Cortical Nodule | 3 | | | | |
| Hypertrophy, Focal | 1 [2.0] | | | | |
| Capsule, Hyperplasia | 5 [1.0] | | | | |
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| Epididymis | (10) | (0) | (0) | (0) | (0) |
| Hypospermia | | | | | |
| Testes | (10) | (0) | (0) | (0) | (0) |
| Germinal Epithelium, Degeneration | | | | | |

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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| B6C3F1 MICE MALE | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG |
|----------------------------------|---------|------------|-------------|------------|-----------|
| HEMATOPOIETIC SYSTEM | | | | | |
| Lymph Node, Mandibular | (9) | (0) | (0) | (0) | (0) |
| Hyperplasia, Histiocytic | 3 [2.0] | | | | |
| Infiltration Cellular, Lipocyte | 4 [1.5] | | | | |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) |
| Necrosis, Lymphoid | | | | | |
| Spleen | (10) | (3) | (0) | (0) | (0) |
| Hematopoietic Cell Proliferation | | 2 [3.0] | | | |
| Thymus | (10) | (0) | (0) | (0) | (0) |
| Atrophy | 1 [1.0] | | | | |
| INTEGUMENTARY SYSTEM | | | | | |
| None | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |
| NERVOUS SYSTEM | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) |
| Hemorrhage | 1 [1.0] | | | | |
| RESPIRATORY SYSTEM | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) |
| Hemorrhage | | | | | |
| SPECIAL SENSES SYSTEM | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) |
| Lens, Degeneration | 1 [3.0] | | | | |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic | 1 [2.0] | | | | |

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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| B6C3F1 MICE MALE | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG |
|------------------|---------|------------|-------------|------------|-----------|
| URINARY SYSTEM | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) |
| Nephropathy | 1 [1.0] | | | | |

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE

250 MG/KG

Disposition Summary

| | |
|----------------------------------|----|
| Animals Initially in Study | 10 |
| Early Deaths | |
| Survivors | |
| Terminal Sacrifice | 10 |
| Animals Examined Microscopically | 10 |

ALIMENTARY SYSTEM

| | |
|--|---------|
| Esophagus | (10) |
| Inflammation, Chronic | 3 [1.0] |
| Liver | (10) |
| Centrilobular, Vacuolization Cytoplasmic | |

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

| | |
|-----------------------------------|---------|
| Adrenal Cortex | (10) |
| Accessory Adrenal Cortical Nodule | |
| Hypertrophy, Focal | |
| Capsule, Hyperplasia | 5 [1.0] |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | |
|-----------------------------------|---------|
| Epididymis | (9) |
| Hypospermia | 1 [4.0] |
| Testes | (10) |
| Germinal Epithelium, Degeneration | 1 [3.0] |

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Lab: SRI

B6C3F1 MICE MALE

250 MG/KG

HEMATOPOIETIC SYSTEM

| | |
|----------------------------------|---------|
| Lymph Node, Mandibular | (10) |
| Hyperplasia, Histiocytic | 4 [1.8] |
| Infiltration Cellular, Lipocyte | 3 [1.3] |
| Lymph Node, Mesenteric | (8) |
| Necrosis, Lymphoid | 3 [2.0] |
| Spleen | (10) |
| Hematopoietic Cell Proliferation | |
| Thymus | (10) |
| Atrophy | |

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

| | |
|------------|------|
| Brain | (10) |
| Hemorrhage | |

RESPIRATORY SYSTEM

| | |
|------------|---------|
| Lung | (10) |
| Hemorrhage | 1 [1.0] |

SPECIAL SENSES SYSTEM

| | |
|-----------------------|---------|
| Eye | (10) |
| Lens, Degeneration | |
| Harderian Gland | (10) |
| Inflammation, Chronic | 2 [1.5] |

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B6C3F1 MICE MALE

250 MG/KG

URINARY SYSTEM

Kidney
Nephropathy

(10)
1 [1.0]

*** END OF MALE ***

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|----------------------------------|----------|------------|-------------|------------|-----------|
| Disposition Summary | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | |
| Survivors | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic | 2 [1.0] | | | | |
| Gallbladder | (10) | (0) | (0) | (0) | (0) |
| Hemorrhage | | | | | |
| Inflammation, Chronic | | | | | |
| Liver | (10) | (10) | (10) | (10) | (10) |
| Eosinophilic Focus | | 1 | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) |
| Atrophy | | | | | |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) |
| Hyperplasia, Lymphoid | 2 [1.0] | | | | |
| CARDIOVASCULAR SYSTEM | | | | | |
| None | | | | | |
| ENDOCRINE SYSTEM | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) |
| Capsule, Hyperplasia | 10 [1.9] | | | | |
| Pituitary Gland | (9) | (0) | (0) | (0) | (0) |
| Pars Distalis, Cyst | | | | | |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) |
| Follicle, Cyst | 1 [2.0] | | | | |
| GENERAL BODY SYSTEM | | | | | |

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|----------------------------------|---------|------------|-------------|------------|-----------|
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| Uterus | (10) | (0) | (1) | (0) | (0) |
| Decidual Reaction | | | 1 [4.0] | | |
| HEMATOPOIETIC SYSTEM | | | | | |
| Lymph Node, Mandibular | (10) | (0) | (0) | (0) | (0) |
| Hyperplasia, Histiocytic | 3 [1.7] | | | | |
| Infiltration Cellular, Lipocyte | 3 [1.3] | | | | |
| Lymph Node, Mesenteric | (10) | (10) | (9) | (10) | (10) |
| Necrosis, Lymphoid | 1 [2.0] | | | | |
| Spleen | (10) | (1) | (0) | (0) | (0) |
| Hematopoietic Cell Proliferation | 2 [1.0] | 1 [2.0] | | | |
| Pigmentation | | | | | |
| Thymus | (10) | (0) | (0) | (0) | (0) |
| Atrophy | 1 [1.0] | | | | |
| INTEGUMENTARY SYSTEM | | | | | |
| None | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |
| NERVOUS SYSTEM | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) |
| Developmental Malformation | | | | | |
| RESPIRATORY SYSTEM | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) |
| Metaplasia, Osseous | | | | | |

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|---|---------|------------|-------------|------------|-----------|
| Nose | (10) | (0) | (0) | (0) | (0) |
| Foreign Body | | | | | |
| Inflammation, Chronic | | | | | |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | | | | | |
| Olfactory Epithelium, Metaplasia, Respiratory | | | | | |
| SPECIAL SENSES SYSTEM | | | | | |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic | | | | | |
| URINARY SYSTEM | | | | | |
| None | | | | | |

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250 MG/KG

Disposition Summary

| | |
|----------------------------------|----|
| Animals Initially in Study | 10 |
| Early Deaths | |
| Survivors | |
| Terminal Sacrifice | 10 |
| Animals Examined Microscopically | 10 |

ALIMENTARY SYSTEM

| | |
|-----------------------|---------|
| Esophagus | (10) |
| Inflammation, Chronic | 5 [1.0] |
| Gallbladder | (10) |
| Hemorrhage | 1 [2.0] |
| Inflammation, Chronic | 1 [1.0] |
| Liver | (10) |
| Eosinophilic Focus | |
| Pancreas | (10) |
| Atrophy | 1 [1.0] |
| Salivary Glands | (10) |
| Hyperplasia, Lymphoid | 2 [1.0] |

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

| | |
|----------------------|----------|
| Adrenal Cortex | (10) |
| Capsule, Hyperplasia | 10 [2.1] |
| Pituitary Gland | (10) |
| Pars Distalis, Cyst | 1 |
| Thyroid Gland | (10) |
| Follicle, Cyst | |

GENERAL BODY SYSTEM

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B6C3F1 MICE FEMALE

250 MG/KG

None

GENITAL SYSTEM

Uterus (10)
Decidual Reaction

HEMATOPOIETIC SYSTEM

Lymph Node, Mandibular (10)
Hyperplasia, Histiocytic 4 [1.8]
Infiltration Cellular, Lipocyte 3 [1.3]
Lymph Node, Mesenteric (10)
Necrosis, Lymphoid
Spleen (10)
Hematopoietic Cell Proliferation
Pigmentation 1 [1.0]
Thymus (10)
Atrophy

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

Brain (10)
Developmental Malformation 1

RESPIRATORY SYSTEM

Lung (10)
Metaplasia, Osseous 1 [1.0]

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B6C3F1 MICE FEMALE

250 MG/KG

| | |
|---|---------|
| Nose | (10) |
| Foreign Body | 1 |
| Inflammation, Chronic | 1 [2.0] |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | 1 [2.0] |
| Olfactory Epithelium, Metaplasia, Respiratory | 1 [2.0] |

SPECIAL SENSES SYSTEM

| | |
|-----------------------|---------|
| Harderian Gland | (10) |
| Inflammation, Chronic | 1 [1.0] |

URINARY SYSTEM

None

*** END OF REPORT ***