

TDMS No. 88105 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 ISOEUGENOL
 CAS Number: 97-54-1
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Requested: 10/04/2006
 Time Report Requested: 13:43:51
 First Dose M/F: 05/09/02 / 05/08/02
 Lab: BNW

| B6C3F1 MICE MALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|----------------------------------|---------|----------|-----------|-----------|
| Disposition Summary | | | | |
| Animals Initially in Study | 50 | 50 | 50 | 50 |
| Early Deaths | | | | |
| Moribund Sacrifice | 7 | 10 | 5 | 7 |
| Natural Death | 4 | 2 | 9 | 16 |
| Survivors | | | | |
| Terminal Sacrifice | 39 | 38 | 36 | 27 |
| Animals Examined Microscopically | 50 | 50 | 50 | 50 |

ALIMENTARY SYSTEM

| | | | | |
|----------------------------|----------|----------|----------|----------|
| Gallbladder | (44) | (47) | (46) | (38) |
| Hyperplasia | | | | 1 (3%) |
| Intestine Large, Colon | (48) | (49) | (46) | (46) |
| Intestine Small, Jejunum | (47) | (48) | (46) | (42) |
| Necrosis | | 1 (2%) | | |
| Ulcer | | | | 1 (2%) |
| Liver | (50) | (50) | (50) | (50) |
| Angiectasis | | | 1 (2%) | |
| Basophilic Focus | 5 (10%) | 5 (10%) | 3 (6%) | 7 (14%) |
| Clear Cell Focus | 16 (32%) | 26 (52%) | 29 (58%) | 13 (26%) |
| Eosinophilic Focus | 8 (16%) | 13 (26%) | 11 (22%) | 5 (10%) |
| Hepatodiaphragmatic Nodule | | | 2 (4%) | |
| Infarct | 2 (4%) | 1 (2%) | | |
| Necrosis | 1 (2%) | | 2 (4%) | 5 (10%) |
| Mesentery | (5) | (4) | (4) | (1) |
| Fat, Necrosis | 5 (100%) | 3 (75%) | 4 (100%) | |
| Pancreas | (50) | (50) | (50) | (49) |
| Atrophy | 2 (4%) | 1 (2%) | 2 (4%) | |
| Hemorrhage | | 1 (2%) | | |
| Hyperplasia | | | | 1 (2%) |
| Necrosis, Fatty | | | 1 (2%) | |
| Duct, Cyst | | | 1 (2%) | |
| Salivary Glands | (50) | (50) | (50) | (50) |
| Stomach, Forestomach | (50) | (49) | (50) | (49) |
| Hyperplasia, Squamous | 7 (14%) | 8 (16%) | 8 (16%) | 14 (29%) |
| Inflammation | 5 (10%) | 8 (16%) | 9 (18%) | 14 (29%) |
| Metaplasia, Hepatocyte | | 1 (2%) | | |

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

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| B6C3F1 MICE MALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|--------------------------------------|----------|----------|-----------|-----------|
| Ulcer | 1 (2%) | 4 (8%) | 4 (8%) | 9 (18%) |
| Stomach, Glandular | (50) | (49) | (49) | (44) |
| Atrophy | | | | 1 (2%) |
| Hyperplasia | | | 1 (2%) | |
| Inflammation | | 1 (2%) | 3 (6%) | 3 (7%) |
| Inflammation, Acute | | | 1 (2%) | 2 (5%) |
| Metaplasia, Hepatocyte | | 1 (2%) | | |
| Mineralization | 1 (2%) | | | |
| Ulcer | | 1 (2%) | 4 (8%) | 5 (11%) |
| CARDIOVASCULAR SYSTEM | | | | |
| Heart | (50) | (50) | (50) | (50) |
| Cardiomyopathy | 9 (18%) | 11 (22%) | 14 (28%) | 12 (24%) |
| Inflammation, Suppurative | 1 (2%) | | 1 (2%) | |
| Mineralization | 1 (2%) | | | 2 (4%) |
| Thrombosis | 1 (2%) | 1 (2%) | 1 (2%) | |
| Artery, Inflammation, Chronic Active | 1 (2%) | 2 (4%) | | 1 (2%) |
| ENDOCRINE SYSTEM | | | | |
| Adrenal Cortex | (50) | (50) | (50) | (49) |
| Hyperplasia | 13 (26%) | 16 (32%) | 12 (24%) | 7 (14%) |
| Hypertrophy | 13 (26%) | 13 (26%) | 14 (28%) | 6 (12%) |
| Adrenal Medulla | (50) | (50) | (50) | (49) |
| Hyperplasia | | 1 (2%) | 2 (4%) | |
| Islets, Pancreatic | (50) | (50) | (50) | (49) |
| Hyperplasia | 3 (6%) | | 1 (2%) | |
| Pituitary Gland | (50) | (48) | (50) | (48) |
| Pars Distalis, Hyperplasia | 1 (2%) | 3 (6%) | 3 (6%) | |
| Thyroid Gland | (50) | (49) | (50) | (49) |
| Follicular Cell, Hyperplasia | | 2 (4%) | | 1 (2%) |
| GENERAL BODY SYSTEM | | | | |
| None | | | | |
| GENITAL SYSTEM | | | | |

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| B6C3F1 MICE MALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|----------------------------------|---------|----------|-----------|-----------|
| Coagulating Gland | (0) | (1) | (0) | (0) |
| Epididymis | (50) | (50) | (50) | (50) |
| Granuloma Sperm | | 1 (2%) | | 1 (2%) |
| Inflammation, Acute | | 1 (2%) | 1 (2%) | |
| Necrosis | | | 1 (2%) | |
| Preputial Gland | (50) | (50) | (50) | (50) |
| Ectasia | 5 (10%) | 4 (8%) | 5 (10%) | 6 (12%) |
| Inflammation, Granulomatous | | 1 (2%) | | |
| Prostate | (50) | (50) | (50) | (50) |
| Inflammation, Chronic Active | | 1 (2%) | | 1 (2%) |
| Seminal Vesicle | (49) | (50) | (50) | (48) |
| Dilatation | | 1 (2%) | | |
| Testes | (50) | (50) | (50) | (50) |
| Atrophy | 1 (2%) | 1 (2%) | | 4 (8%) |
| Inflammation, Suppurative | | 1 (2%) | | |
| HEMATOPOIETIC SYSTEM | | | | |
| Bone Marrow | (50) | (50) | (50) | (50) |
| Atrophy | | | 1 (2%) | |
| Hyperplasia, Reticulum Cell | | | | 1 (2%) |
| Necrosis | | 1 (2%) | | |
| Lymph Node | (1) | (0) | (2) | (2) |
| Lymph Node, Mandibular | (49) | (49) | (50) | (47) |
| Lymph Node, Mesenteric | (48) | (50) | (50) | (48) |
| Spleen | (50) | (50) | (50) | (49) |
| Depletion Cellular | | | | 2 (4%) |
| Hematopoietic Cell Proliferation | | | 1 (2%) | 1 (2%) |
| Thymus | (48) | (48) | (48) | (42) |
| INTEGUMENTARY SYSTEM | | | | |
| Skin | (50) | (50) | (50) | (50) |
| Inflammation, Acute | 1 (2%) | | | |
| Inflammation, Chronic Active | | 3 (6%) | 1 (2%) | 2 (4%) |
| MUSCULOSKELETAL SYSTEM | | | | |
| Bone | (50) | (50) | (50) | (50) |
| Arthrosis | 1 (2%) | | | |

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

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| B6C3F1 MICE MALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|---|---------|----------|-----------|-----------|
| Skeletal Muscle | (1) | (0) | (0) | (0) |
| NERVOUS SYSTEM | | | | |
| Brain | (50) | (50) | (50) | (50) |
| Inflammation, Granulomatous | | | | 1 (2%) |
| Necrosis | | 2 (4%) | | |
| RESPIRATORY SYSTEM | | | | |
| Lung | (50) | (49) | (50) | (50) |
| Thrombosis | 1 (2%) | | 1 (2%) | |
| Alveolar Epithelium, Hyperplasia | 3 (6%) | 4 (8%) | 4 (8%) | 2 (4%) |
| Alveolus, Infiltration Cellular, Histiocyte | | 1 (2%) | | |
| Bronchiole, Hyperplasia | 1 (2%) | | 1 (2%) | |
| Nose | (50) | (50) | (50) | (50) |
| Polyp, Inflammatory | | 1 (2%) | | |
| Glands, Hyperplasia | 3 (6%) | 34 (68%) | 49 (98%) | 48 (96%) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | | 6 (12%) | 26 (52%) | 19 (38%) |
| Olfactory Epithelium, Atrophy | 5 (10%) | 13 (26%) | 36 (72%) | 41 (82%) |
| Olfactory Epithelium, Degeneration | 1 (2%) | 1 (2%) | 7 (14%) | 6 (12%) |
| Olfactory Epithelium, Inflammation, Granulomatous | | | | 1 (2%) |
| Olfactory Epithelium, Metaplasia, Squamous | | | 2 (4%) | 1 (2%) |
| Olfactory Epithelium, Respiratory Metaplasia | 4 (8%) | 31 (62%) | 47 (94%) | 49 (98%) |
| Pleura | (0) | (1) | (0) | (0) |
| SPECIAL SENSES SYSTEM | | | | |
| Eye | (48) | (48) | (46) | (43) |
| Inflammation, Acute | | 1 (2%) | | |
| Cornea, Inflammation, Chronic Active | | 1 (2%) | 1 (2%) | |
| Harderian Gland | (49) | (50) | (50) | (49) |
| Hyperplasia | 3 (6%) | 4 (8%) | 4 (8%) | 4 (8%) |
| URINARY SYSTEM | | | | |
| Kidney | (50) | (50) | (50) | (49) |

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|--|----------|----------------|--------------------|-----------|
| Infarct | 1 (2%) | 1 (2%) | 2 (4%) | 1 (2%) |
| Inflammation, Suppurative Metaplasia, Osseous | | 2 (4%) | | 2 (4%) |
| Nephropathy | 47 (94%) | 48 (96%) | 1 (2%) 47 (94%) | 47 (96%) |
| Renal Tubule, Hyperplasia | 2 (4%) | 2 (4%) | 1 (2%) | 2 (4%) |
| Urinary Bladder Inflammation, Chronic Active | (49) | (50) 1 (2%) | (50) | (45) |

*** END OF MALE ***

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|----------------------------------|---------|----------|-----------|-----------|
| Disposition Summary | | | | |
| Animals Initially in Study | 50 | 50 | 50 | 50 |
| Early Deaths | | | | |
| Accidently Killed | 2 | | | 1 |
| Moribund Sacrifice | 5 | 7 | 5 | 5 |
| Natural Death | 8 | 4 | 7 | 11 |
| Survivors | | | | |
| Terminal Sacrifice | 34 | 39 | 38 | 33 |
| Animals Examined Microscopically | 49 | 50 | 50 | 50 |
| ALIMENTARY SYSTEM | | | | |
| Gallbladder | (42) | (47) | (47) | (40) |
| Degeneration, Hyaline | | | 1 (2%) | |
| Intestine Large, Cecum | (46) | (47) | (45) | (42) |
| Inflammation, Acute | | | | 1 (2%) |
| Necrosis | | | | 1 (2%) |
| Intestine Large, Colon | (47) | (47) | (47) | (47) |
| Intestine Large, Rectum | (47) | (48) | (45) | (46) |
| Necrosis | | | | 1 (2%) |
| Intestine Small, Duodenum | (42) | (47) | (45) | (40) |
| Intestine Small, Ileum | (45) | (47) | (46) | (44) |
| Intestine Small, Jejunum | (44) | (48) | (45) | (45) |
| Liver | (49) | (50) | (49) | (50) |
| Amyloid Deposition | | | 1 (2%) | |
| Angiectasis | 2 (4%) | 2 (4%) | 2 (4%) | |
| Basophilic Focus | 5 (10%) | 4 (8%) | 8 (16%) | 4 (8%) |
| Clear Cell Focus | 1 (2%) | 1 (2%) | 2 (4%) | |
| Eosinophilic Focus | 5 (10%) | 5 (10%) | 4 (8%) | 1 (2%) |
| Fatty Change | 3 (6%) | 1 (2%) | 1 (2%) | |
| Hematopoietic Cell Proliferation | 1 (2%) | 1 (2%) | | |
| Inflammation, Chronic | | | | 1 (2%) |
| Mineralization | | | | 2 (4%) |
| Mixed Cell Focus | 1 (2%) | | | |
| Necrosis | 3 (6%) | | 1 (2%) | 8 (16%) |
| Hepatocyte, Mitotic Alteration | | | 1 (2%) | |
| Mesentery | (15) | (14) | (14) | (6) |
| Fat, Hemorrhage | | | 1 (7%) | |

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| B6C3F1 MICE FEMALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|------------------------------|----------|-----------|-----------|-----------|
| Fat, Necrosis | 14 (93%) | 14 (100%) | 13 (93%) | 6 (100%) |
| Pancreas | (47) | (50) | (47) | (49) |
| Amyloid Deposition | | 2 (4%) | | |
| Atrophy | | 1 (2%) | 1 (2%) | |
| Basophilic Focus | 1 (2%) | 2 (4%) | 1 (2%) | 1 (2%) |
| Hyperplasia | | | | 1 (2%) |
| Duct, Cyst | 1 (2%) | 1 (2%) | | |
| Salivary Glands | (49) | (50) | (50) | (50) |
| Necrosis | | 1 (2%) | | |
| Stomach, Forestomach | (48) | (50) | (49) | (50) |
| Hyperplasia, Squamous | 2 (4%) | 8 (16%) | 5 (10%) | 8 (16%) |
| Inflammation | 2 (4%) | 8 (16%) | 5 (10%) | 8 (16%) |
| Ulcer | 2 (4%) | 4 (8%) | 3 (6%) | 4 (8%) |
| Stomach, Glandular | (46) | (48) | (47) | (48) |
| Amyloid Deposition | | 1 (2%) | | |
| Inflammation | | 1 (2%) | 1 (2%) | 6 (13%) |
| Mineralization | 1 (2%) | | | |
| Ulcer | | 1 (2%) | 1 (2%) | 7 (15%) |
| CARDIOVASCULAR SYSTEM | | | | |
| Blood Vessel | (2) | (1) | (1) | (2) |
| Mineralization | 1 (50%) | | | 1 (50%) |
| Heart | (49) | (50) | (50) | (50) |
| Cardiomyopathy | 2 (4%) | 2 (4%) | | 3 (6%) |
| Inflammation, Suppurative | | 1 (2%) | | 2 (4%) |
| Mineralization | 3 (6%) | 2 (4%) | 2 (4%) | 5 (10%) |
| Thrombosis | | 1 (2%) | | 2 (4%) |
| ENDOCRINE SYSTEM | | | | |
| Adrenal Cortex | (48) | (50) | (49) | (50) |
| Amyloid Deposition | | 1 (2%) | 1 (2%) | |
| Hyperplasia | 4 (8%) | 2 (4%) | 4 (8%) | 2 (4%) |
| Hypertrophy | | 1 (2%) | 3 (6%) | 1 (2%) |
| Necrosis | | | | 1 (2%) |
| Vacuolization Cytoplasmic | 1 (2%) | | | |
| Adrenal Medulla | (48) | (50) | (49) | (50) |
| Hyperplasia | 1 (2%) | | 1 (2%) | 2 (4%) |
| Islets, Pancreatic | (47) | (50) | (48) | (49) |

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|----------------------------------|----------|----------|-----------|-----------|
| Hyperplasia | 1 (2%) | 1 (2%) | 1 (2%) | 2 (4%) |
| Pituitary Gland | (47) | (48) | (50) | (50) |
| Pars Distalis, Hyperplasia | 9 (19%) | 17 (35%) | 6 (12%) | 9 (18%) |
| Thyroid Gland | (48) | (50) | (49) | (50) |
| Follicular Cell, Hyperplasia | 1 (2%) | | | 1 (2%) |
| GENERAL BODY SYSTEM | | | | |
| None | | | | |
| GENITAL SYSTEM | | | | |
| Clitoral Gland | (47) | (49) | (49) | (48) |
| Ovary | (48) | (50) | (50) | (50) |
| Angiectasis | 2 (4%) | | | 1 (2%) |
| Cyst | 5 (10%) | 12 (24%) | 5 (10%) | 4 (8%) |
| Thrombosis | | 1 (2%) | | |
| Uterus | (48) | (50) | (50) | (50) |
| Angiectasis | 2 (4%) | 3 (6%) | 2 (4%) | |
| Inflammation, Suppurative | | 1 (2%) | | |
| Thrombosis | | | 1 (2%) | |
| Endometrium, Hyperplasia, Cystic | 24 (50%) | 32 (64%) | 19 (38%) | 21 (42%) |
| HEMATOPOIETIC SYSTEM | | | | |
| Bone Marrow | (48) | (49) | (50) | (50) |
| Necrosis | | 1 (2%) | | |
| Lymph Node | (4) | (5) | (3) | (2) |
| Lymph Node, Mandibular | (49) | (50) | (50) | (50) |
| Lymph Node, Mesenteric | (47) | (49) | (47) | (50) |
| Hyperplasia, Lymphoid | | 1 (2%) | | |
| Inflammation, Acute | | | | 1 (2%) |
| Spleen | (48) | (50) | (49) | (50) |
| Amyloid Deposition | | | 1 (2%) | |
| Depletion Cellular | | | | 9 (18%) |
| Hematopoietic Cell Proliferation | 1 (2%) | 5 (10%) | 2 (4%) | |
| Hyperplasia, Lymphoid | | 1 (2%) | | |
| Necrosis | 1 (2%) | | | |
| Thymus | (47) | (50) | (49) | (47) |

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| B6C3F1 MICE FEMALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|---|---------|----------|-----------|-----------|
| INTEGUMENTARY SYSTEM | | | | |
| Mammary Gland | (48) | (50) | (50) | (50) |
| Hyperplasia | 1 (2%) | | | |
| Skin | (49) | (50) | (50) | (50) |
| Hemorrhage | 1 (2%) | | | |
| Inflammation, Chronic Active | | | 1 (2%) | |
| Necrosis | 1 (2%) | 1 (2%) | | |
| MUSCULOSKELETAL SYSTEM | | | | |
| Bone | (49) | (50) | (50) | (50) |
| Skeletal Muscle | (0) | (1) | (0) | (0) |
| NERVOUS SYSTEM | | | | |
| Brain | (49) | (50) | (50) | (50) |
| Demyelination | | 2 (4%) | | |
| Gliosis | 1 (2%) | | | |
| Necrosis | | 1 (2%) | | 1 (2%) |
| Peripheral Nerve | (2) | (2) | (1) | (0) |
| Radicular Neuropathy | 1 (50%) | 1 (50%) | 1 (100%) | |
| RESPIRATORY SYSTEM | | | | |
| Lung | (48) | (50) | (50) | (50) |
| Hemorrhage | | 1 (2%) | | |
| Inflammation, Suppurative | | 1 (2%) | | |
| Mineralization | 1 (2%) | | | |
| Thrombosis | | | | 1 (2%) |
| Alveolar Epithelium, Hyperplasia | 2 (4%) | 1 (2%) | 4 (8%) | |
| Bronchiole, Hyperplasia | | | | 1 (2%) |
| Bronchiole, Necrosis | | | | 1 (2%) |
| Nose | (48) | (50) | (50) | (50) |
| Thrombosis | | | | 1 (2%) |
| Glands, Hyperplasia | 6 (13%) | 38 (76%) | 49 (98%) | 49 (98%) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | | 4 (8%) | 18 (36%) | 12 (24%) |

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| B6C3F1 MICE FEMALE | 0 MG/KG | 75 MG/KG | 150 MG/KG | 300 MG/KG |
|--|----------|----------|-----------|-----------|
| Olfactory Epithelium, Atrophy | 3 (6%) | 8 (16%) | 36 (72%) | 43 (86%) |
| Olfactory Epithelium, Degeneration | | | 1 (2%) | 2 (4%) |
| Olfactory Epithelium, Respiratory Metaplasia | 6 (13%) | 37 (74%) | 49 (98%) | 50 (100%) |
| Respiratory Epithelium, Necrosis | | | | 1 (2%) |
| SPECIAL SENSES SYSTEM | | | | |
| Eye | (44) | (47) | (46) | (42) |
| Cataract | | | 1 (2%) | 1 (2%) |
| Degeneration | | | 1 (2%) | 1 (2%) |
| Harderian Gland | (46) | (50) | (49) | (48) |
| Hyperplasia | 5 (11%) | 5 (10%) | 6 (12%) | 2 (4%) |
| URINARY SYSTEM | | | | |
| Kidney | (47) | (50) | (49) | (49) |
| Amyloid Deposition | 1 (2%) | 1 (2%) | 1 (2%) | |
| Inflammation, Suppurative | | | | 1 (2%) |
| Nephropathy | 23 (49%) | 30 (60%) | 22 (45%) | 33 (67%) |
| Bilateral, Papilla, Necrosis | | 1 (2%) | | 4 (8%) |
| Papilla, Mineralization | | | | 1 (2%) |
| Papilla, Necrosis | | | 1 (2%) | 14 (29%) |
| Renal Tubule, Necrosis | | 1 (2%) | | 6 (12%) |
| Urinary Bladder | (47) | (49) | (47) | (46) |

*** END OF REPORT ***