

Experiment Number: 99024-05
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Androstenedione
CAS Number: 63-05-8

Date Report Requested: 10/21/2014
Time Report Requested: 18:29:39
First Dose M/F: NA / NA
Lab: SRI

| | |
|-----------------------------|------------|
| C Number: | C99024C |
| Lock Date: | 11/15/2002 |
| Cage Range: | All |
| Date Range: | All |
| Reasons For Removal: | All |
| Removal Date Range: | All |
| Treatment Groups: | All |
| Study Gender: | Both |
| PWG Approval Date | NONE |

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Species/Strain: Rat/F 344/N

Lab: SRI

| F 344/N Rat MALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|---|-----------|----------|---------|----------|----------|-----------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation, Focal | 2 (20%) | | | 2 (20%) | 1 (10%) | 5 (50%) |
| Hepatodiaphragmatic Nodule | 1 (10%) | 2 (20%) | 2 (20%) | 1 (10%) | | 1 (10%) |
| Inflammation, Chronic, Focal | 5 (50%) | 4 (40%) | 4 (40%) | 4 (40%) | 4 (40%) | 2 (20%) |
| Vacuolization Cytoplasmic, Focal | 9 (90%) | 7 (70%) | 9 (90%) | 8 (80%) | 9 (90%) | 10 (100%) |
| Mesentery | (0) | (1) | (0) | (0) | (0) | (0) |
| Necrosis, Fatty, Focal | | 1 (100%) | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Acinus, Atrophy, Focal | 4 (40%) | | | | | 2 (20%) |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Parotid GI, Basophilic Focus, Multiple | 10 (100%) | | | | | 7 (70%) |
| Submandibul GI, Vacuolization Cytoplasmic | | | | | | 2 (20%) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Granulomatous | 1 (10%) | | | | | |

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

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Test Compound: Androstenedione

Time Report Requested: 18:29:39

Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: SRI

| F 344/N Rat MALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|-----------------------------------|----------|-----------|-----------|-----------|----------|-----------|
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Cardiomyopathy, Focal | 9 (90%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (90%) | 10 (100%) |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (10) | (10) | (10) | (10) | (10) |
| Accessory Adrenal Cortical Nodule | | | | 1 (10%) | | 1 (10%) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |
| Islets, Pancreatic | (1) | (0) | (0) | (0) | (0) | (0) |
| Hyperplasia, Focal | 1 (100%) | | | | | |
| Parathyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Pars Distalis, Cyst | | | | | | 1 (10%) |
| Thyroid Gland | (10) | (10) | (10) | (10) | (10) | (10) |
| Cyst | | | | | | 1 (10%) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Epididymis | (10) | (0) | (0) | (0) | (0) | (10) |
| Preputial Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Prostate | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Lymphocyte | | 1 (10%) | | | | |
| Seminal Vesicle | (10) | (0) | (0) | (0) | (0) | (10) |
| Testes | (10) | (1) | (0) | (0) | (0) | (10) |
| Atrophy | | 1 (100%) | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node | (1) | (0) | (0) | (0) | (0) | (1) |
| Mediastinal, Hemorrhage | 1 (100%) | | | | | 1 (100%) |

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

Experiment Number: 99024-05

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Date Report Requested: 10/21/2014

Test Type: 90-DAY

Test Compound: Androstenedione

Time Report Requested: 18:29:39

Route: GAVAGE

CAS Number: 63-05-8

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: SRI

| F 344/N Rat MALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|--|---------|---------|---------|----------|----------|----------|
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (1) | (10) |
| Necrosis | 2 (20%) | | | | | 1 (10%) |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (10) | (5) | (8) | (8) | (8) | (9) |
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) | (10) |
| Alveolus, Hemorrhage, Focal | 2 (20%) | | | | | 1 (10%) |
| Alveolus, Infiltration Cellular, Histiocyte, Focal | 2 (20%) | | | | | |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Nephropathy | 4 (40%) | | | | | 5 (50%) |
| Renal Tubule, Mineralization, Focal | 1 (10%) | | | | | |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

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Experiment Number: 99024-05

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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Test Compound: Androstenedione

CAS Number: 63-05-8

Date Report Requested: 10/21/2014

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First Dose M/F: NA / NA

Lab: SRI

END OF MALE DATA

Experiment Number: 99024-05

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Test Compound: Androstenedione

Time Report Requested: 18:29:39

Route: GAVAGE

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Species/Strain: Rat/F 344/N

Lab: SRI

| F 344/N Rat FEMALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|---|----------|---------|---------|-----------|-----------|----------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation, Focal | 1 (10%) | | | | | |
| Hepatodiaphragmatic Nodule | 1 (10%) | 2 (20%) | 5 (50%) | 1 (10%) | 1 (10%) | 1 (10%) |
| Inflammation, Chronic, Focal | 9 (90%) | 9 (90%) | 6 (60%) | 10 (100%) | 10 (100%) | 8 (80%) |
| Mesentery | (2) | (0) | (0) | (0) | (0) | (0) |
| Necrosis, Fatty, Focal | 2 (100%) | | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Acinus, Atrophy, Focal | 1 (10%) | | | | | |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Parotid G1, Atrophy | 1 (10%) | | | | | 1 (10%) |
| Parotid G1, Basophilic Focus | 1 (10%) | | | | | |
| Parotid G1, Basophilic Focus, Multiple | 4 (40%) | | | | | 8 (80%) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |

CARDIOVASCULAR SYSTEM

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Lab: SRI

| F 344/N Rat FEMALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|---|---------|---------|----------|----------|----------|----------|
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Cardiomyopathy, Focal | 7 (70%) | 7 (70%) | 7 (70%) | 7 (70%) | 9 (90%) | 9 (90%) |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (10) | (10) | (10) | (10) | (10) |
| Accessory Adrenal Cortical Nodule | 1 (10%) | 1 (10%) | | | 1 (10%) | |
| Adrenal Medulla | (10) | (0) | (1) | (0) | (0) | (10) |
| Cytoplasmic Alteration, Focal | | | 1 (100%) | | | |
| Parathyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Lymphocyte | 1 (10%) | | | | | |
| Ultimobranchial Cyst | | | | | | 2 (20%) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Clitoral Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Ovary | (10) | (10) | (10) | (10) | (10) | (10) |
| Cyst | | | | 1 (10%) | | |
| Uterus | (10) | (10) | (10) | (10) | (10) | (10) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node | (6) | (0) | (0) | (0) | (0) | (2) |
| Mediastinal, Hemorrhage | | | | | | 1 (50%) |
| Pancreatic, Infiltration Cellular, Histiocyte | 5 (83%) | | | | | 1 (50%) |
| Lymph Node, Mandibular | (0) | (0) | (0) | (0) | (0) | (1) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Hyperplasia, Lymphoid | 1 (10%) | | | | | |
| Infiltration Cellular, Histiocyte | | | | | | 1 (10%) |

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Species/Strain: Rat/F 344/N

Lab: SRI

| F 344/N Rat FEMALE | 0 MG/KG | 1 MG/KG | 5 MG/KG | 10 MG/KG | 20 MG/KG | 50 MG/KG |
|--|---------|---------|---------|----------|----------|----------|
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |
| Necrosis | 2 (20%) | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (10) | (10) | (10) | (10) | (10) | (10) |
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) | (10) |
| Alveolus, Hemorrhage, Focal | 1 (10%) | | | | | 5 (50%) |
| Alveolus, Infiltration Cellular, Histiocyte, Focal | 1 (10%) | | | | | 1 (10%) |
| Inflammation, Chronic, Focal | 1 (10%) | | | | | 2 (20%) |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Lymphocyte | 1 (10%) | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Nephropathy | | | | | | 1 (10%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

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

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