

Experiment Number: 88032-03

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: Oxymetholone

CAS Number: 434-07-1

Date Report Requested: 10/19/2014

Time Report Requested: 04:57:01

First Dose M/F: NA / NA

Lab: BAT

C Number: C88032B

Lock Date: 02/03/1993

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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CAS Number: 434-07-1

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First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|---|-----------|----------|-----------|-----------|-----------|------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | 1 |
| Natural Death | | | | | | 1 |
| Survivors | | | | | | |
| Natural Death | | | | | | 1 |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 9 | 9 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (1) | (10) |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (9) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (1) | (9) |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (1) | (10) |
| Parasite Metazoan | 1 (10%) | | | | | |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (9) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (9) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (1) | (9) |
| Liver | (10) | (0) | (0) | (2) | (1) | (9) |
| Hematopoietic Cell Proliferation | 1 (10%) | | | | | |
| Hepatodiaphragmatic Nodule | | | | 2 (100%) | | 1 (11%) |
| Pancreas | (10) | (0) | (0) | (0) | (1) | (9) |
| Salivary Glands | (10) | (0) | (0) | (0) | (1) | (9) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (2) | (9) |
| Necrosis, Diffuse | | | | | 1 (50%) | |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (1) | (9) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Blood Vessel | (10) | (0) | (0) | (0) | (1) | (9) |
| Heart | (10) | (10) | (10) | (10) | (10) | (9) |
| Myocardium, Degeneration, Chronic | 10 (100%) | 8 (80%) | 10 (100%) | 10 (100%) | 9 (90%) | 9 (100%) |

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

Experiment Number: 88032-03
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: Oxymetholone
CAS Number: 434-07-1

Date Report Requested: 10/19/2014
Time Report Requested: 04:57:01
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|----------------------------------|---------|----------|-----------|-----------|-----------|------------|
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (10) | (10) | (10) | (10) | (9) |
| Hypertrophy, Focal | 1 (10%) | | | | | |
| Vacuolization Cytoplasmic | 9 (90%) | 6 (60%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (100%) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (1) | (9) |
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (1) | (9) |
| Parathyroid Gland | (8) | (0) | (0) | (0) | (1) | (8) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (1) | (9) |
| Craniophar Dct, Cyst | | | | | | 1 (11%) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (1) | (9) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Epididymis | (10) | (0) | (0) | (0) | (1) | (10) |
| Preputial Gland | (9) | (0) | (0) | (0) | (1) | (9) |
| Prostate | (10) | (0) | (0) | (0) | (1) | (9) |
| Inflammation, Chronic | 1 (10%) | | | | | |
| Seminal Vesicle | (10) | (0) | (0) | (0) | (1) | (9) |
| Testes | (10) | (0) | (0) | (0) | (1) | (10) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (1) | (10) |
| Lymph Node, Mandibular | (10) | (0) | (0) | (0) | (0) | (8) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (1) | (9) |
| Spleen | (10) | (0) | (0) | (0) | (1) | (9) |
| Lymph Follic, Depletion Cellular | | | | | 1 (100%) | |
| Thymus | (10) | (0) | (0) | (0) | (1) | (9) |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (9) | (9) | (7) | (8) | (10) | (8) |

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

Experiment Number: 88032-03
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: Oxymetholone
CAS Number: 434-07-1

Date Report Requested: 10/19/2014
Time Report Requested: 04:57:01
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat MALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|---|-----------|-----------|-----------|-----------|-----------|------------|
| Dilatation | | | 7 (100%) | 8 (100%) | 10 (100%) | 8 (100%) |
| Skin | (10) | (0) | (0) | (0) | (1) | (10) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (1) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (1) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (1) | (9) |
| Alveolus, Foreign Body | | | | | 1 (100%) | |
| Alveolus, Inflammation, Chronic Active | 1 (10%) | | | | | |
| Nose | (10) | (0) | (0) | (0) | (1) | (10) |
| Turbinate, Inflammation, Chronic Active | 8 (80%) | | | | | |
| Trachea | (10) | (0) | (0) | (0) | (1) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (10) | (10) | (10) | (10) | (9) |
| Cortex, Hyperplasia, Tubular | 1 (10%) | | | | | |
| Nephropathy | 10 (100%) | | | | | |
| Regeneration, Diffuse | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (100%) |
| Renal Tubule, Mineralization, Diffuse | | 1 (10%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (100%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (1) | (9) |

END OF MALE DATA

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

Experiment Number: 88032-03
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: Oxymetholone
CAS Number: 434-07-1

Date Report Requested: 10/19/2014
Time Report Requested: 04:57:02
First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat FEMALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|---|---------|----------|-----------|-----------|-----------|------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | 1 |
| Dosing Accident | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 9 |
| 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) | (2) | (0) | (1) | (0) | (10) |
| Hepatodiaphragmatic Nodule | 1 (10%) | 2 (100%) | | 1 (100%) | | |
| Inflammation, Chronic Active, Diffuse | 1 (10%) | | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Atrophy | 1 (10%) | | | | | |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Blood Vessel | (10) | (0) | (0) | (0) | (0) | (10) |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Myocardium, Degeneration, Chronic | 3 (30%) | 6 (60%) | 7 (70%) | 9 (90%) | 9 (90%) | 9 (90%) |
| ENDOCRINE SYSTEM | | | | | | |

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

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Route: Gavage
Species/Strain: Rat/F 344/N

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Date Report Requested: 10/19/2014
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First Dose M/F: NA / NA
Lab: BAT

| F 344/N Rat FEMALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|-------------------------------|---------|-----------|-----------|-----------|-----------|------------|
| Adrenal Cortex | (10) | (10) | (10) | (10) | (10) | (10) |
| Vacuolization Cytoplasmic | | | | 8 (80%) | 10 (100%) | 9 (90%) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (0) | (10) |
| Parathyroid Gland | (9) | (0) | (0) | (0) | (0) | (6) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (8) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Clitoral Gland | (8) | (0) | (0) | (0) | (0) | (10) |
| Ovary | (10) | (10) | (10) | (10) | (10) | (10) |
| Atrophy | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (90%) |
| Periovarn Tiss, Cyst | | | 1 (10%) | 1 (10%) | 1 (10%) | |
| Uterus | (10) | (10) | (10) | (10) | (10) | (10) |
| Cervix, Hydrometra | | | | | | 1 (10%) |
| Hydrometra | 1 (10%) | 2 (20%) | 9 (90%) | 10 (100%) | 10 (100%) | 9 (90%) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Mandibular | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (10) | (8) | (8) | (9) | (8) | (10) |
| Hyperplasia | | 5 (63%) | 8 (100%) | 9 (100%) | 8 (100%) | 9 (90%) |
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |
| MUSCULOSKELETAL SYSTEM | | | | | | |

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

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Route: Gavage

Species/Strain: Rat/F 344/N

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Lab: BAT

| F 344/N Rat FEMALE | 0 MG/KG | 80 MG/KG | 160 MG/KG | 315 MG/KG | 625 MG/KG | 1250 MG/KG |
|---|-----------|-----------|-----------|-----------|-----------|------------|
| 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, Foreign Body | | | | | | 1 (10%) |
| Alveolus, Inflammation, Chronic Active | 2 (20%) | | | | | 1 (10%) |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Turbinate, Inflammation, Chronic Active | 5 (50%) | | | | | 1 (10%) |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (10) | (10) | (10) | (10) | (10) |
| Cortex, Hyperplasia, Tubular | 1 (10%) | | | | | |
| Nephropathy | 3 (30%) | | | | | |
| Regeneration, Diffuse | | 1 (10%) | 8 (80%) | 9 (90%) | 9 (90%) | 10 (100%) |
| Renal Tubule, Mineralization, Diffuse | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 9 (90%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

** END OF REPORT **

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