

**Experiment Number:** 88032-04  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** Oxymetholone  
**CAS Number:** 434-07-1

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 18:21:55  
**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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First Dose M/F: NA / NA

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Lab: BAT

| B6C3F1 Mouse MALE                | 0 MG/KG | 160 MG/KG | 320 MG/KG | 630 MG/KG | 1250 MG/KG | 2500 MG/KG |
|----------------------------------|---------|-----------|-----------|-----------|------------|------------|
| <b>Disposition Summary</b>       |         |           |           |           |            |            |
| 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         |
| <b>ALIMENTARY SYSTEM</b>         |         |           |           |           |            |            |
| Esophagus                        | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Gallbladder                      | (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)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Pancreas                         | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Salivary Glands                  | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Stomach, Forestomach             | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Epithelium, Hyperplasia, Focal   |         |           |           |           |            | 1 (10%)    |
| Stomach, Glandular               | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Epithelium, Mineralization       |         |           |           |           |            | 2 (20%)    |
| <b>CARDIOVASCULAR SYSTEM</b>     |         |           |           |           |            |            |
| Blood Vessel                     | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Heart                            | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| <b>ENDOCRINE SYSTEM</b>          |         |           |           |           |            |            |
| Adrenal Cortex                   | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Adrenal Medulla                  | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |

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

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Route: GAVAGE

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First Dose M/F: NA / NA

Species/Strain: Mouse/B6C3F1

Lab: BAT

| B6C3F1 Mouse MALE      | 0 MG/KG | 160 MG/KG | 320 MG/KG | 630 MG/KG | 1250 MG/KG | 2500 MG/KG |
|------------------------|---------|-----------|-----------|-----------|------------|------------|
| Islets, Pancreatic     | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Parathyroid Gland      | (9)     | (0)       | (0)       | (0)       | (0)        | (5)        |
| Pituitary Gland        | (8)     | (0)       | (0)       | (0)       | (0)        | (10)       |
| Thyroid Gland          | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| GENERAL BODY SYSTEM    |         |           |           |           |            |            |
| None                   |         |           |           |           |            |            |
| GENITAL SYSTEM         |         |           |           |           |            |            |
| Epididymis             | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Preputial Gland        | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Prostate               | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Seminal Vesicle        | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Testes                 | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| HEMATOPOIETIC SYSTEM   |         |           |           |           |            |            |
| Bone Marrow            | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Lymph Node, Mandibular | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Lymph Node, Mesenteric | (9)     | (0)       | (0)       | (0)       | (0)        | (10)       |
| Spleen                 | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Thymus                 | (10)    | (0)       | (0)       | (0)       | (0)        | (9)        |
| INTEGUMENTARY SYSTEM   |         |           |           |           |            |            |
| 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)       |
| Nose                   | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |

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

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**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**  
**Test Compound:** Oxymetholone  
**CAS Number:** 434-07-1

**Date Report Requested:** 10/21/2014  
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**First Dose M/F:** NA / NA  
**Lab:** BAT

| <b>B6C3F1 Mouse MALE</b> | <b>0 MG/KG</b> | <b>160 MG/KG</b> | <b>320 MG/KG</b> | <b>630 MG/KG</b> | <b>1250 MG/KG</b> | <b>2500 MG/KG</b> |
|--------------------------|----------------|------------------|------------------|------------------|-------------------|-------------------|
| Trachea                  | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| SPECIAL SENSES SYSTEM    |                |                  |                  |                  |                   |                   |
| None                     |                |                  |                  |                  |                   |                   |
| URINARY SYSTEM           |                |                  |                  |                  |                   |                   |
| Kidney                   | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| Urinary Bladder          | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |

\*\*\*END OF MALE DATA\*\*\*

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 Lab: BAT

| B6C3F1 Mouse FEMALE                    | 0 MG/KG | 160 MG/KG | 320 MG/KG | 630 MG/KG | 1250 MG/KG | 2500 MG/KG |
|--|---------|-----------|-----------|-----------|------------|------------|
| <b>Disposition Summary</b>             |         |           |           |           |            |            |
| 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         |
| <b>ALIMENTARY SYSTEM</b>               |         |           |           |           |            |            |
| Esophagus                              | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Gallbladder                            | (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)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Pancreas                               | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Salivary Glands                        | (10)    | (10)      | (10)      | (10)      | (10)       | (10)       |
| Parotid G1, Atrophy                    |         |           |           |           | 4 (40%)    | 9 (90%)    |
| Submandibul G1, Cytoplasmic Alteration |         | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%)  | 10 (100%)  |
| Stomach, Forestomach                   | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Stomach, Glandular                     | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Epithelium, Mineralization             | 1 (10%) |           |           |           |            |            |
| <b>CARDIOVASCULAR SYSTEM</b>           |         |           |           |           |            |            |
| Blood Vessel                           | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Heart                                  | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| <b>ENDOCRINE SYSTEM</b>                |         |           |           |           |            |            |
| Adrenal Cortex                         | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |

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

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| B6C3F1 Mouse FEMALE | 0 MG/KG | 160 MG/KG | 320 MG/KG | 630 MG/KG | 1250 MG/KG | 2500 MG/KG |
|---------------------|---------|-----------|-----------|-----------|------------|------------|
| Adrenal Medulla     | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Islets, Pancreatic  | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |
| Parathyroid Gland   | (9)     | (0)       | (0)       | (0)       | (0)        | (10)       |
| Cyst                | 1 (11%) |           |           |           |            |            |
| Pituitary Gland     | (10)    | (0)       | (0)       | (0)       | (0)        | (9)        |
| Thyroid Gland       | (10)    | (0)       | (0)       | (0)       | (0)        | (10)       |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

|                         |      |           |           |           |           |           |
|-------------------------|------|-----------|-----------|-----------|-----------|-----------|
| Clitoral Gland          | (9)  | (10)      | (10)      | (10)      | (10)      | (10)      |
| Hyperplasia             |      | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Ovary                   | (10) | (10)      | (10)      | (10)      | (10)      | (10)      |
| Corpus Luteum, Atrophy  |      |           | 7 (70%)   | 10 (100%) | 10 (100%) | 10 (100%) |
| Interstit Cell, Atrophy |      |           | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Uterus                  | (10) | (0)       | (0)       | (0)       | (0)       | (10)      |

HEMATOPOIETIC SYSTEM

|                        |      |     |     |     |     |      |
|------------------------|------|-----|-----|-----|-----|------|
| Bone Marrow            | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Mandibular | (9)  | (0) | (0) | (0) | (0) | (9)  |
| 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) | (0) | (0) | (0) | (0) | (10) |
| Skin          | (10) | (0) | (0) | (0) | (0) | (10) |

MUSCULOSKELETAL SYSTEM

|      |      |     |     |     |     |      |
|------|------|-----|-----|-----|-----|------|
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
|------|------|-----|-----|-----|-----|------|

NERVOUS SYSTEM

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| <b>B6C3F1 Mouse FEMALE</b>              | <b>0 MG/KG</b> | <b>160 MG/KG</b> | <b>320 MG/KG</b> | <b>630 MG/KG</b> | <b>1250 MG/KG</b> | <b>2500 MG/KG</b> |
|---|----------------|------------------|------------------|------------------|-------------------|-------------------|
| Brain                                   | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| <b>RESPIRATORY SYSTEM</b>               |                |                  |                  |                  |                   |                   |
| Lung                                    | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| Nose                                    | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| Infiltration Cellular, Mast Cell, Focal | 1 (10%)        |                  |                  |                  |                   |                   |
| Trachea                                 | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |
| <b>SPECIAL SENSES SYSTEM</b>            |                |                  |                  |                  |                   |                   |
| None                                    |                |                  |                  |                  |                   |                   |
| <b>URINARY SYSTEM</b>                   |                |                  |                  |                  |                   |                   |
| Kidney                                  | (10)           | (10)             | (10)             | (10)             | (10)              | (10)              |
| Bow Cap Pari, Metaplasia                |                | 10 (100%)        | 10 (100%)        | 10 (100%)        | 10 (100%)         | 10 (100%)         |
| Urinary Bladder                         | (10)           | (0)              | (0)              | (0)              | (0)               | (10)              |

**\*\* END OF REPORT \*\***