

**Experiment Number:** 99930-97  
**Test Type:** SPECIAL STUDY  
**Route:** DOSED FEED  
**Species/Strain:** Rat/CD

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

**Test Compound:** Endocrine disruptor (Genistein)

**CAS Number:** 446-72-0

**Date Report Requested:** 10/17/2014

**Time Report Requested:** 12:41:39

**First Dose M/F:** NA / NA

**Lab:** NCTR

|                             |              |
|-----------------------------|--------------|
| <b>C Number:</b>            | MG96005      |
| <b>Lock Date:</b>           | Not Entered. |
| <b>Cage Range:</b>          | All          |
| <b>Date Range:</b>          | All          |
| <b>Reasons For Removal:</b> | All          |
| <b>Removal Date Range:</b>  | All          |
| <b>Treatment Groups:</b>    | All          |
| <b>Study Gender:</b>        | Both         |
| <b>PWG Approval Date</b>    | NONE         |

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| CD Rat MALE                              | F2 | 0 PPM    | F2 | 5 PPM | F2 | 100 PPM | F2 | 500 PPM  |
|--|----|----------|----|-------|----|---------|----|----------|
| <b>Disposition Summary</b>               |    |          |    |       |    |         |    |          |
| Animals Initially In Study               |    | 25       |    | 25    |    | 25      |    | 25       |
| Early Deaths                             |    |          |    |       |    |         |    |          |
| Survivors                                |    |          |    |       |    |         |    |          |
| Terminal Sacrifice                       |    | 25       |    | 25    |    | 25      |    | 25       |
| Animals Examined Microscopically         |    | 25       |    | 25    |    | 25      |    | 25       |
| <b>ALIMENTARY SYSTEM</b>                 |    |          |    |       |    |         |    |          |
| Liver                                    |    | (25)     |    | (0)   |    | (0)     |    | (25)     |
| Inflammation, Chronic                    |    | 18 (72%) |    |       |    |         |    | 22 (88%) |
| Malformation                             |    | 1 (4%)   |    |       |    |         |    |          |
| Necrosis                                 |    | 1 (4%)   |    |       |    |         |    | 1 (4%)   |
| Vacuolization Cytoplasmic                |    | 3 (12%)  |    |       |    |         |    | 2 (8%)   |
| <b>CARDIOVASCULAR SYSTEM</b>             |    |          |    |       |    |         |    |          |
| None                                     |    |          |    |       |    |         |    |          |
| <b>ENDOCRINE SYSTEM</b>                  |    |          |    |       |    |         |    |          |
| Adrenal Cortex                           |    | (25)     |    | (0)   |    | (0)     |    | (25)     |
| Accessory Adrenal Cortical Nodule        |    | 2 (8%)   |    |       |    |         |    |          |
| Vacuolization Cytoplasmic                |    |          |    |       |    |         |    | 1 (4%)   |
| Adrenal Medulla                          |    | (25)     |    | (0)   |    | (0)     |    | (25)     |
| Pituitary Gland                          |    | (25)     |    | (0)   |    | (0)     |    | (25)     |
| Pars Distalis, Cyst                      |    | 1 (4%)   |    |       |    |         |    |          |
| Pars Distalis, Cyst, Multiple            |    | 2 (8%)   |    |       |    |         |    | 1 (4%)   |
| Pars Distalis, Vacuolization Cytoplasmic |    | 3 (12%)  |    |       |    |         |    |          |
| Thyroid Gland                            |    | (25)     |    | (0)   |    | (0)     |    | (25)     |
| <b>GENERAL BODY SYSTEM</b>               |    |          |    |       |    |         |    |          |
| None                                     |    |          |    |       |    |         |    |          |
| <b>GENITAL SYSTEM</b>                    |    |          |    |       |    |         |    |          |

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

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**First Dose M/F:** NA / NA  
**Lab:** NCTR

| CD Rat MALE                       | F2       | 0 PPM | F2       | 5 PPM | F2       | 100 PPM | F2       | 500 PPM |
|-----------------------------------|----------|-------|----------|-------|----------|---------|----------|---------|
| Coagulating Gland                 | (24)     |       | (25)     |       | (24)     |         | (24)     |         |
| Epididymis                        | (25)     |       | (25)     |       | (25)     |         | (25)     |         |
| Degeneration                      |          |       |          |       |          |         | 1 (4%)   |         |
| Hypospermia                       |          |       |          |       | 1 (4%)   |         | 1 (4%)   |         |
| Infiltration Cellular, Lymphocyte | 1 (4%)   |       |          |       |          |         |          |         |
| Prostate                          | (5)      |       | (9)      |       | (5)      |         | (6)      |         |
| Prostate, Dorsal Lobe             | (25)     |       | (25)     |       | (25)     |         | (25)     |         |
| Epithelium, Hyperplasia           |          |       |          |       | 1 (4%)   |         |          |         |
| Inflammation, Chronic             | 7 (28%)  |       | 4 (16%)  |       | 6 (24%)  |         | 6 (24%)  |         |
| Inflammation, Suppurative         | 4 (16%)  |       | 6 (24%)  |       | 8 (32%)  |         | 7 (28%)  |         |
| Prostate, Ventral Lobe            | (25)     |       | (25)     |       | (25)     |         | (25)     |         |
| Inflammation, Chronic             | 19 (76%) |       | 15 (60%) |       | 15 (60%) |         | 17 (68%) |         |
| Inflammation, Suppurative         | 6 (24%)  |       | 2 (8%)   |       | 6 (24%)  |         | 5 (20%)  |         |
| Rete Testes                       | (25)     |       | (22)     |       | (25)     |         | (20)     |         |
| Dilatation                        |          |       |          |       | 2 (8%)   |         |          |         |
| Seminal Vesicle                   | (25)     |       | (25)     |       | (25)     |         | (25)     |         |
| Dilatation                        | 1 (4%)   |       | 1 (4%)   |       |          |         | 2 (8%)   |         |
| Epithelium, Hyperplasia           |          |       | 1 (4%)   |       |          |         |          |         |
| Inflammation, Chronic             |          |       | 1 (4%)   |       | 1 (4%)   |         |          |         |
| Testes                            | (25)     |       | (25)     |       | (25)     |         | (24)     |         |
| Seminif Tub, Degeneration         | 3 (12%)  |       |          |       | 2 (8%)   |         | 1 (4%)   |         |
| <b>HEMATOPOIETIC SYSTEM</b>       |          |       |          |       |          |         |          |         |
| Bone Marrow                       | (25)     |       | (0)      |       | (0)      |         | (25)     |         |
| Spleen                            | (25)     |       | (0)      |       | (0)      |         | (25)     |         |
| Adventitia, Inflammation, Chronic | 1 (4%)   |       |          |       |          |         |          |         |
| Hyperplasia, Stromal              |          |       |          |       |          |         | 1 (4%)   |         |
| Pigmentation                      | 5 (20%)  |       |          |       |          |         | 4 (16%)  |         |
| Thymus                            | (25)     |       | (0)      |       | (1)      |         | (25)     |         |
| Atrophy                           |          |       |          |       | 1 (100%) |         |          |         |

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

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**Test Compound:** Endocrine disruptor (Genistein)  
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**First Dose M/F:** NA / NA  
**Lab:** NCTR

| CD Rat MALE                   | F2 0 PPM | F2 5 PPM | F2 100 PPM | F2 500 PPM |
|-------------------------------|----------|----------|------------|------------|
| <b>INTEGUMENTARY SYSTEM</b>   |          |          |            |            |
| Mammary Gland                 | (24)     | (25)     | (25)       | (25)       |
| Alveolus, Hyperplasia         | 2 (8%)   |          | 7 (28%)    | 18 (72%)   |
| Duct, Hyperplasia             |          |          | 1 (4%)     | 10 (40%)   |
| Skin                          | (25)     | (0)      | (0)        | (25)       |
| <b>MUSCULOSKELETAL SYSTEM</b> |          |          |            |            |
| Bone, Femur                   | (25)     | (0)      | (0)        | (25)       |
| <b>NERVOUS SYSTEM</b>         |          |          |            |            |
| None                          |          |          |            |            |
| <b>RESPIRATORY SYSTEM</b>     |          |          |            |            |
| None                          |          |          |            |            |
| <b>SPECIAL SENSES SYSTEM</b>  |          |          |            |            |
| None                          |          |          |            |            |
| <b>URINARY SYSTEM</b>         |          |          |            |            |
| Kidney                        | (25)     | (25)     | (25)       | (25)       |
| Capsule, Fat, Cyst            |          | 1 (4%)   | 1 (4%)     | 1 (4%)     |
| Casts Protein                 |          | 2 (8%)   |            |            |
| Cortex, Cyst                  |          | 1 (4%)   |            | 2 (8%)     |
| Inflammation, Chronic         | 20 (80%) | 16 (64%) | 16 (64%)   | 23 (92%)   |
| Pelvis, Dilatation            |          |          |            | 1 (4%)     |
| Renal Tubule, Dilatation      | 8 (32%)  | 1 (4%)   | 5 (20%)    | 6 (24%)    |
| Renal Tubule, Mineralization  |          | 1 (4%)   | 4 (16%)    | 6 (24%)    |
| Renal Tubule, Regeneration    | 8 (32%)  | 3 (12%)  | 8 (32%)    | 9 (36%)    |
| Urinary Bladder               | (0)      | (0)      | (0)        | (1)        |

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

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

| CD Rat FEMALE                           | F2 | 0 PPM  | F2 | 5 PPM    | F2 | 100 PPM | F2 | 500 PPM |
|---|----|--------|----|----------|----|---------|----|---------|
| <b>Disposition Summary</b>              |    |        |    |          |    |         |    |         |
| Animals Initially In Study              |    | 25     |    | 25       |    | 25      |    | 25      |
| Early Deaths                            |    |        |    |          |    |         |    |         |
| Survivors                               |    |        |    |          |    |         |    |         |
| Terminal Sacrifice                      |    | 25     |    | 25       |    | 25      |    | 25      |
| Animals Examined Microscopically        |    | 25     |    | 25       |    | 25      |    | 25      |
| <b>ALIMENTARY SYSTEM</b>                |    |        |    |          |    |         |    |         |
| Liver                                   |    | (25)   |    | (2)      |    | (0)     |    | (25)    |
| Bile Duct, Inflammation                 |    |        |    |          |    |         |    | 1 (4%)  |
| Developmental Malformation              |    |        |    | 2 (100%) |    |         |    | 1 (4%)  |
| Inflammation, Chronic Active, Focal     |    |        |    |          |    |         |    | 1 (4%)  |
| Median Lobe, Developmental Malformation |    | 1 (4%) |    |          |    |         |    | 1 (4%)  |
| Necrosis, Focal                         |    |        |    |          |    |         |    | 1 (4%)  |
| Pancreas                                |    | (1)    |    | (0)      |    | (0)     |    | (0)     |
| <b>CARDIOVASCULAR SYSTEM</b>            |    |        |    |          |    |         |    |         |
| None                                    |    |        |    |          |    |         |    |         |
| <b>ENDOCRINE SYSTEM</b>                 |    |        |    |          |    |         |    |         |
| Adrenal Cortex                          |    | (25)   |    | (0)      |    | (0)     |    | (25)    |
| Adrenal Medulla                         |    | (25)   |    | (0)      |    | (0)     |    | (25)    |
| Pituitary Gland                         |    | (25)   |    | (0)      |    | (0)     |    | (25)    |
| Thyroid Gland                           |    | (25)   |    | (0)      |    | (0)     |    | (25)    |
| Cyst                                    |    |        |    |          |    |         |    | 1 (4%)  |
| <b>GENERAL BODY SYSTEM</b>              |    |        |    |          |    |         |    |         |
| None                                    |    |        |    |          |    |         |    |         |
| <b>GENITAL SYSTEM</b>                   |    |        |    |          |    |         |    |         |
| Ovary                                   |    | (25)   |    | (25)     |    | (25)    |    | (25)    |
| Cyst                                    |    |        |    |          |    |         |    | 1 (4%)  |

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 Test Compound: Endocrine disruptor (Genistein)  
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Date Report Requested: 10/17/2014  
 Time Report Requested: 12:41:40  
 First Dose M/F: NA / NA  
 Lab: NCTR

| CD Rat FEMALE                 | F2 0 PPM | F2 5 PPM | F2 100 PPM | F2 500 PPM |
|-------------------------------|----------|----------|------------|------------|
| Diestrus                      | 7 (28%)  | 6 (24%)  | 6 (24%)    | 6 (24%)    |
| Estrus                        | 5 (20%)  | 7 (28%)  | 6 (24%)    | 2 (8%)     |
| Metestrus                     | 6 (24%)  | 4 (16%)  | 6 (24%)    | 7 (28%)    |
| Proestrus                     | 7 (28%)  | 8 (32%)  | 7 (28%)    | 10 (40%)   |
| Oviduct                       | (25)     | (25)     | (25)       | (25)       |
| Uterus                        | (25)     | (25)     | (25)       | (25)       |
| Decidual Reaction             | 24 (96%) | 24 (96%) | 24 (96%)   | 22 (88%)   |
| Diestrus                      | 7 (28%)  | 6 (24%)  | 6 (24%)    | 6 (24%)    |
| Estrus                        | 5 (20%)  | 7 (28%)  | 6 (24%)    | 2 (8%)     |
| Metestrus                     | 6 (24%)  | 4 (16%)  | 6 (24%)    | 7 (28%)    |
| Proestrus                     | 7 (28%)  | 8 (32%)  | 7 (28%)    | 10 (40%)   |
| Vagina                        | (24)     | (23)     | (24)       | (23)       |
| Diestrus                      | 7 (29%)  | 6 (26%)  | 6 (25%)    | 6 (26%)    |
| Estrus                        | 6 (25%)  | 8 (35%)  | 8 (33%)    | 2 (9%)     |
| Metestrus                     | 6 (25%)  | 4 (17%)  | 6 (25%)    | 7 (30%)    |
| Proestrus                     | 5 (21%)  | 5 (22%)  | 4 (17%)    | 8 (35%)    |
| <b>HEMATOPOIETIC SYSTEM</b>   |          |          |            |            |
| Bone Marrow                   | (25)     | (0)      | (0)        | (25)       |
| Spleen                        | (25)     | (0)      | (0)        | (25)       |
| Thymus                        | (25)     | (0)      | (0)        | (25)       |
| <b>INTEGUMENTARY SYSTEM</b>   |          |          |            |            |
| Mammary Gland                 | (24)     | (25)     | (25)       | (25)       |
| Alveolus, Hyperplasia         | 18 (75%) | 15 (60%) | 16 (64%)   | 21 (84%)   |
| Skin                          | (25)     | (0)      | (0)        | (25)       |
| <b>MUSCULOSKELETAL SYSTEM</b> |          |          |            |            |
| Bone, Femur                   | (25)     | (0)      | (0)        | (25)       |
| <b>NERVOUS SYSTEM</b>         |          |          |            |            |
| None                          |          |          |            |            |

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

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**First Dose M/F:** NA / NA  
**Lab:** NCTR

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| <b>CD Rat FEMALE</b>                 | <b>F2</b> | <b>0 PPM</b> | <b>F2</b> | <b>5 PPM</b> | <b>F2</b> | <b>100 PPM</b> | <b>F2</b> | <b>500 PPM</b> |
|--------------------------------------|-----------|--------------|-----------|--------------|-----------|----------------|-----------|----------------|
| <hr/>                                |           |              |           |              |           |                |           |                |
| RESPIRATORY SYSTEM                   |           |              |           |              |           |                |           |                |
| None                                 |           |              |           |              |           |                |           |                |
| <hr/>                                |           |              |           |              |           |                |           |                |
| SPECIAL SENSES SYSTEM                |           |              |           |              |           |                |           |                |
| None                                 |           |              |           |              |           |                |           |                |
| <hr/>                                |           |              |           |              |           |                |           |                |
| URINARY SYSTEM                       |           |              |           |              |           |                |           |                |
| Kidney                               |           | (25)         |           | (25)         |           | (25)           |           | (25)           |
| Bilateral, Cyst                      |           |              |           | 1 (4%)       |           |                |           |                |
| Cyst                                 |           |              |           | 2 (8%)       |           | 2 (8%)         |           | 2 (8%)         |
| Infarct                              |           |              |           |              |           |                |           | 1 (4%)         |
| Inflammation, Chronic Active         |           |              |           | 2 (8%)       |           | 2 (8%)         |           |                |
| Mineralization                       |           | 20 (80%)     |           | 21 (84%)     |           | 23 (92%)       |           | 19 (76%)       |
| Parenchym Cell, Proliferation, Focal |           |              |           | 1 (4%)       |           |                |           |                |
| Pelvis, Dilatation                   |           |              |           | 1 (4%)       |           |                |           |                |
| Renal Tubule, Dilatation, Focal      |           |              |           |              |           | 1 (4%)         |           |                |

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