Experiment Number: 99930-99
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

Time Report Requested: 14:12:42

Date Report Requested: 10/22/2014

First Dose M/F: NA / NA

Lab: NCTR

C Number: MG96005

Lock Date: Not Entered.

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

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: 10/22/2014 Time Report Requested: 14:12:42

First Dose M/F: NA / NA

CD Rat MALE	FO 0 PPM	F0 5 PPM	F0 100 PPM	F0 500 PPN
Disposition Summary				
Animals Initially In Study	25	25	25	25
Early Deaths				
Natural Death	1			
Survivors				
Terminal Sacrifice	24	25	25	25
Animals Examined Microscopically	25	25	25	25
ALIMENTARY SYSTEM				
Liver	(24)	(6)	(0)	(25)
Fibrosis	1 (4%)	1 (17%)		
Hemorrhage				1 (4%)
Hepatodiaphragmatic Nodule	3 (13%)	1 (17%)		2 (8%)
Inflammation, Chronic	18 (75%)			19 (76%)
Malformation		3 (50%)		2 (8%)
Necrosis	2 (8%)			4 (16%)
Perivascular, Fibrosis		1 (17%)		
Vacuolization Cytoplasmic	7 (29%)			8 (32%)
Mesentery	(0)	(0)	(0)	(1)
Fat, Inflammation, Chronic				1 (100%)
Salivary Glands	(1)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(1)	(0)	(0)	(0)
Heart	(1)	(0)	(0)	(0)
ENDOCRINE SYSTEM				
Adrenal Cortex	(23)	(0)	(0)	(25)
Accessory Adrenal Cortical Nodule	1 (4%)			1 (4%)
Adrenal Medulla	(22)	(0)	(0)	(25)
Parathyroid Gland	(1)	(0)	(1)	(0)

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

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) **Test Compound:** Endocrine disruptor (Genistein)

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

Date Report Requested: 10/22/2014 Time Report Requested: 14:12:42

First Dose M/F: NA / NA

Lab: NCTR

Route: DOSED FEED Species/Strain: Rat/CD

CD Rat MALE	FO 0 PPM	FO 5 PPM	F0 100 PPM	F0 500 PPM
Pituitary Gland	(24)	(0)	(0)	(25)
Pars Distalis, Cyst, Multiple				2 (8%)
Thyroid Gland	(24)	(0)	(0)	(25)
Inflammation, Chronic	1 (4%)			2 (8%)
GENERAL BODY SYSTEM  None				
GENITAL SYSTEM				
Coagulating Gland	(23)	(24)	(22)	(25)
Epididymis	(24)	(25)	(25)	(25)
Hypospermia	2 (8%)			1 (4%)
Infiltration Cellular, Lymphocyte	1 (4%)	2 (8%)	2 (8%)	
Preputial Gland	(0)	(0)	(0)	(1)
Duct, Dilatation				1 (100%)
Inflammation, Suppurative				1 (100%)
Prostate	(2)	(5)	(4)	(4)
Prostate, Dorsal Lobe	(23)	(25)	(25)	(25)
Inflammation, Chronic	6 (26%)	4 (16%)	6 (24%)	10 (40%)
Inflammation, Suppurative	8 (35%)	9 (36%)	7 (28%)	16 (64%)
Prostate, Ventral Lobe	(23)	(25)	(25)	(25)
Inflammation, Chronic	17 (74%)	16 (64%)	19 (76%)	17 (68%)
Inflammation, Suppurative	2 (9%)	2 (8%)	2 (8%)	2 (8%)
Rete Testes	(24)	(25)	(24)	(25)
Dilatation	2 (8%)			
Seminal Vesicle	(24)	(23)	(25)	(24)
Dilatation	3 (13%)	1 (4%)		1 (4%)
Epithelium, Degeneration	1 (4%)			
Malformation		1 (4%)		
Testes	(25)	(25)	(25)	(25)
Autolysis	1 (4%)			

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

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: 10/22/2014
Time Report Requested: 14:12:42

First Dose M/F: NA / NA

CD Rat MALE	FO OPPM	FO 5 PPM	F0 100 PPM	F0 500 PPM
Edema				1 (4%)
Seminif Tub, Degeneration	3 (12%)	2 (8%)	2 (8%)	2 (8%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(24)	(0)	(0)	(25)
Spleen	(24)	(0)	(0)	(25)
Adventitia, Inflammation, Chronic				2 (8%)
Capsule, Fibrosis				1 (4%)
Capsule, Inflammation, Chronic				1 (4%)
Pigmentation	5 (21%)			9 (36%)
Thymus	(24)	(0)	(0)	(23)
INTEGUMENTARY SYSTEM				
Mammary Gland	(23)	(24)	(23)	(24)
Alveolus, Hyperplasia	1 (4%)	3 (13%)	2 (9%)	5 (21%)
Duct, Hyperplasia				1 (4%)
Skin	(25)	(0)	(0)	(25)
MUSCULOSKELETAL SYSTEM				
Bone, Femur	(25)	(0)	(0)	(25)
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(24)	(0)	(1)	(25)
Casts Protein	1 (4%)			1 (4%)
Cortex, Cyst	, ,		1 (100%)	

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

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: 10/22/2014
Time Report Requested: 14:12:42

First Dose M/F: NA / NA

Lab: NCTR

	CD Rat MALE	FO 0 PPM	F0	5 PPM	F0	100 PPM	F0	500 PPM
_	Hyaline Droplet	2 (8%)						
	Inflammation, Chronic	20 (83%)					1	8 (72%)
	Interstitium, Fibrosis	2 (8%)						
	Renal Tubule, Dilatation	8 (33%)					;	8 (32%)
	Renal Tubule, Mineralization	1 (4%)						
	Renal Tubule, Regeneration	10 (42%)						7 (28%)

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

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: 10/22/2014
Time Report Requested: 14:12:42

First Dose M/F: NA / NA

CD Rat FEMALE	FO 0 PPM	F0 5 PPM	F0 100 PPM	F0 500 PPM
Disposition Summary				
Animals Initially In Study	26	25	26	25
Early Deaths				
Moribund	1		1	
Survivors				
Terminal Sacrifice	25	25	25	25
Animals Examined Microscopically	26	25	26	25
ALIMENTARY SYSTEM				
Esophagus	(1)	(0)	(1)	(0)
Dilatation	1 (100%)			
Intestine Large, Cecum	(1)	(0)	(1)	(0)
Intestine Large, Colon	(1)	(0)	(1)	(0)
Intestine Small, Duodenum	(1)	(0)	(1)	(0)
Intestine Small, Ileum	(1)	(0)	(1)	(0)
Intestine Small, Jejunum	(1)	(0)	(1)	(0)
Liver	(26)	(1)	(1)	(25)
Crystals			1 (100%)	
Developmental Malformation	3 (12%)	1 (100%)		
Inflammation, Chronic Active	1 (4%)			2 (8%)
Left Lat Lobe, Developmental Malformation				2 (8%)
Median Lobe, Developmental Malformation				1 (4%)
Pancreas	(1)	(0)	(1)	(0)
Salivary Glands	(1)	(0)	(1)	(0)
Stomach, Forestomach	(1)	(0)	(1)	(0)
Stomach, Glandular	(1)	(0)	(1)	(0)
CARDIOVASCULAR SYSTEM				
Heart	(1)	(0)	(1)	(0)
Cardiomyopathy	1 (100%)			

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

**Experiment Number:** 99930-99

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: 10/22/2014
Time Report Requested: 14:12:42

First Dose M/F: NA / NA

CD Rat FEMALE	FO OPPM	F0 5 PPM	F0 100 PPM	F0 500 PPI
ENDOCRINE SYSTEM				
Adrenal Cortex	(26)	(0)	(1)	(25)
Adrenal Medulla	(26)	(0)	(1)	(25)
Bilateral, Vacuolization Cytoplasmic	1 (4%)			
Pituitary Gland	(26)	(0)	(1)	(25)
Thyroid Gland	(25)	(0)	(1)	(25)
GENERAL BODY SYSTEM  None				
GENITAL SYSTEM				
Clitoral Gland	(0)	(1)	(1)	(1)
Abscess				1 (100%)
Inflammation, Chronic Active		1 (100%)		
Keratin Cyst				1 (100%)
Ovary	(26)	(25)	(26)	(25)
Corpus Luteum, Hypertrophy			1 (4%)	
Diestrus	10 (38%)	9 (36%)	7 (27%)	6 (24%)
Estrus	2 (8%)	2 (8%)	1 (4%)	
Metestrus	6 (23%)	6 (24%)	8 (31%)	13 (52%)
Proestrus	8 (31%)	8 (32%)	9 (35%)	6 (24%)
Oviduct	(26)	(25)	(26)	(25)
Estrus				1 (4%)
Uterus	(26)	(25)	(26)	(25)
Decidual Reaction	24 (92%)	24 (96%)	24 (92%)	23 (92%)
Diestrus	10 (38%)	9 (36%)	7 (27%)	6 (24%)
Estrus	2 (8%)	2 (8%)	1 (4%)	
Infiltration Cellular, Eosinophil	1 (4%)			
Metestrus	7 (27%)	5 (20%)	8 (31%)	13 (52%)
Pregnancy			1 (4%)	
Proestrus	7 (27%)	8 (32%)	9 (35%)	6 (24%)

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

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: 10/22/2014 Time Report Requested: 14:12:42

First Dose M/F: NA / NA

Lab: NCTR

CD Rat FEMALE	FO 0 PPM	F0 5 PPM	F0 100 PPM	F0 500 PPM
Vagina	(26)	(25)	(26)	(25)
Diestrus	10 (38%)	9 (36%)	8 (31%)	7 (28%)
Estrus	3 (12%)	6 (24%)	2 (8%)	1 (4%)
Infiltration Cellular, Eosinophil	1 (4%)			
Keratin Cyst				1 (4%)
Metestrus	7 (27%)	6 (24%)	8 (31%)	12 (48%)
Mucocyte, Hyperplasia			1 (4%)	
Mucocyte, Hypertrophy	1 (4%)		1 (4%)	
Proestrus	6 (23%)	4 (16%)	7 (27%)	5 (20%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(26)	(0)	(1)	(25)
Lymph Node, Mandibular	(1)	(0)	(1)	(0)
Lymph Node, Mesenteric	(1)	(0)	(1)	(0)
Spleen	(25)	(0)	(1)	(24)
Pigmentation	1 (4%)			
Thymus	(26)	(0)	(1)	(25)
Atrophy	1 (4%)			
NTEGUMENTARY SYSTEM				
Mammary Gland	(25)	(25)	(26)	(25)
Alveolus, Hyperplasia	10 (40%)	12 (48%)	8 (31%)	8 (32%)
Duct, Hyperplasia			1 (4%)	
Lobules, Hyperplasia	3 (12%)	1 (4%)	3 (12%)	1 (4%)
Skin	(26)	(0)	(2)	(25)
MUSCULOSKELETAL SYSTEM				
Bone	(1)	(0)	(0)	(0)
Necrosis, Focal	1 (100%)			
Bone, Femur	(26)	(0)	(1)	(25)

**NERVOUS SYSTEM** 

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

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

Test Compound: Endocrine disruptor (Genistein)

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

Date Report Requested: 10/22/2014 Time Report Requested: 14:12:42

First Dose M/F: NA / NA

Lab: NCTR

CD Rat FEMALE	FO 0 PPM	F0 5 PPM	F0 100 PPM	F0 500 PPM
Brain, Brain Stem	(1)	(0)	(1)	(0)
Brain, Cerebellum	(1)	(0)	(1)	(0)
Brain, Cerebrum	(1)	(0)	(1)	(0)
RESPIRATORY SYSTEM				
Lung	(1)	(0)	(1)	(0)
Inflammation, Multifocal, Chronic Active	1 (100%)			
Nose	(1)	(0)	(1)	(0)
Trachea	(0)	(0)	(1)	(0)
SPECIAL SENSES SYSTEM				
Eye	(1)	(0)	(0)	(0)
Cornea, Edema	1 (100%)		,	
URINARY SYSTEM				
Kidney	(26)	(25)	(26)	(25)
Apoptosis			1 (4%)	
Bilateral, Nephropathy	1 (4%)			
Bilateral, Parenchym Cell, Proliferation			1 (4%)	
Bilateral, Pelvis, Dilatation		1 (4%)		
Inflammation, Chronic Active		1 (4%)	2 (8%)	
Left, Cyst				1 (4%)
Left, Pelvis, Dilatation	1 (4%)			
Mineralization	17 (65%)	21 (84%)	22 (85%)	14 (56%)
Pelvis, Dilatation	1 (4%)			
Urinary Bladder	(0)	(0)	(1)	(0)

<sup>\*\*</sup> END OF REPORT \*\*

**Experiment Number:** 99930-99

Test Type: SPECIAL STUDY

Route: DOSED FEED

Species/Strain: Rat/CD