Route: DOSED FEED

Species/Strain: Rat/CD

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/23/2014 AVERAGE SEVERITY GRADES[b]

**Test Compound:** ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number: 57-63-6** 

Time Report Requested: 12:57:57

First Dose M/F: NA / NA

Lab: NCTR

C Number: MG96006

Lock Date: Not Entered.

**Cage Range:** ΑII

**Date Range:** ΑII

**Reasons For Removal:** ΑII

**Removal Date Range:** ΑII

**Treatment Groups:** ΑII

**Study Gender:** Both

**PWG Approval Date NONE** 

Route: DOSED FEED

Species/Strain: Rat/CD

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 12:57:57

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number:** 57-63-6

Time Report Requested: 12:57:57

First Dose M/F: NA / NA

CD Rat MALE	F4 CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Disposition Summary				
Animals Initially In Study	25	25	26	25
Early Deaths				
Moribund Sacrifice			1	
Survivors				
Terminal Sacrifice	25	25	25	25
Animals Examined Microscopically	25	25	26	25
ALIMENTARY SYSTEM				
Esophagus	(0)	(0)	(1)	(0)
Liver	(25)	(1)	(2)	(25)
Bile Duct, Hyperplasia			1 [3.0]	1 [1.0]
Cyst	1			
Hepatocyte, Degeneration			1 [4.0]	
Hepatocyte, Necrosis			1 [3.0]	
Hepatodiaphragmatic Nodule			1	
Infiltration Cellular, Lymphocyte	1 [1.0]		1 [4.0]	1 [1.0]
Inflammation, Chronic Active	13 [1.0]			10 [1.1]
Vacuolization Cytoplasmic				1 [1.0]
Pancreas	(0)	(0)	(1)	(0)
Acinar Cell, Degeneration			1 [4.0]	
Infiltration Cellular, Lymphocyte			1 [4.0]	
CARDIOVASCULAR SYSTEM				
Blood Vessel	(0)	(0)	(1)	(0)
Heart	(0)	(0)	(1)	(0)
ENDOCRINE SYSTEM				
Adrenal Cortex	(25)	(0)	(1)	(25)
Accessory Adrenal Cortical Nodule	1			

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: DOSED FEED

Species/Strain: Rat/CD

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 12:57:58

**Test Compound:** ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number:** 57-63-6

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

CD Rat MALE	F4	CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Vacuolization Cytoplasmic		4 [1.3]			2 [1.5]
Adrenal Medulla		(25)	(0)	(1)	(25)
Pituitary Gland		(25)	(0)	(2)	(25)
Pars Distalis, Cyst				1	2
Thyroid Gland		(25)	(0)	(0)	(25)
Cyst, Squamous		6			4
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Coagulating Gland		(25)	(25)	(26)	(24)
Bilateral, Developmental Malformation		1			1
Developmental Malformation		9	9	6	10
Hypoplasia				1 [4.0]	
Epididymis		(25)	(25)	(26)	(25)
Atrophy					1 [2.0]
Hypoplasia				1 [4.0]	
Hypospermia					1 [4.0]
Preputial Gland		(0)	(2)	(1)	(0)
Duct, Dilatation			2 [3.0]		
Inflammation, Suppurative			2 [4.0]	1 [3.0]	
Prostate, Dorsal/Lateral Lobe		(6)	(7)	(10)	(6)
Hypoplasia				1 [4.0]	
Inflammation, Suppurative		6 [1.3]	7 [1.1]	9 [1.4]	6 [1.2]
Prostate, Dorsal/lateral Lobe		(19)	(18)	(16)	(19)
Prostate, Ventral Lobe		(25)	(25)	(26)	(25)
Hypoplasia				1 [4.0]	
Infiltration Cellular, Lymphocyte		14 [1.4]	9 [1.3]	13 [1.7]	16 [1.4]
Inflammation, Suppurative		1 [1.0]	1 [2.0]		

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

**Experiment Number: 99920-95** Test Type: SPECIAL STUDY Route: DOSED FEED

Species/Strain: Rat/CD

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 12:57:58

**Test Compound:** ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number:** 57-63-6

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

CD Rat MALE	F4	CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Rete Testes		(25)	(24)	(26)	(25)
Dilatation					1 [2.0]
Seminal Vesicle		(25)	(25)	(26)	(25)
Hypoplasia				1 [4.0]	
Testes		(25)	(25)	(26)	(25)
Hypoplasia				1 [4.0]	
Seminif Tub, Degeneration		1 [1.0]	3 [1.0]		1 [4.0]
HEMATOPOIETIC SYSTEM					
Bone Marrow		(25)	(0)	(1)	(25)
Spleen		(25)	(0)	(1)	(25)
Congestion				1 [3.0]	
Hyperplasia, Lymphoid				1 [3.0]	1 [2.0]
Thymus		(25)	(0)	(1)	(25)
Atrophy				1 [4.0]	
INTEGUMENTARY SYSTEM					
Mammary Gland		(25)	(25)	(25)	(25)
Alveolus, Hyperplasia		3 [1.0]	5 [2.2]	5 [2.0]	7 [1.9]
Duct, Hyperplasia		1 [1.0]		2 [1.0]	
Skin		(0)	(0)	(1)	(0)
MUSCULOSKELETAL SYSTEM					
Bone		(25)	(0)	(1)	(25)
NERVOUS SYSTEM					
Brain		(0)	(0)	(1)	(0)
Spinal Cord		(0)	(0)	(1)	(0)
RESPIRATORY SYSTEM					
Lung		(0)	(0)	(1)	(0)
Infiltration Cellular, Histiocyte		•		1 [2.0]	

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: DOSED FEED

Species/Strain: Rat/CD

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014
Time Report Requested: 12:57:58

**Test Compound:** ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number: 57-63-6** 

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

CD Rat MALE	F4	CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Peribronchiolr, Infiltration Cellular, Lymphocyte				1 [4.0]	
Trachea		(0)	(0)	(1)	(0)
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
Kidney		(25)	(0)	(1)	(25)
Cortex, Cyst		1			4
Epithelium, Pelvis, Hyperplasia					1 [2.0]
Hyaline Droplet					4 [1.0]
Infiltration Cellular, Lymphocyte		14 [1.0]		1 [4.0]	13 [1.2]
Inflammation, Chronic		1 [1.0]			
Interstitium, Fibrosis				1 [2.0]	2 [1.5]
Renal Tubule, Dilatation		2 [1.0]			5 [1.4]
Renal Tubule, Mineralization					1 [1.0]
Renal Tubule, Regeneration		8 [1.0]			11 [1.0]
Urinary Bladder		(0)	(0)	(1)	(0)

<sup>\*\*\*</sup>END OF MALE DATA\*\*\*

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: DOSED FEED

Species/Strain: Rat/CD

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 12:57:58

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number:** 57-63-6

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

CD Rat FEMALE	F4	CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRI
Disposition Summary					
Animals Initially In Study		25	25	26	25
Early Deaths					
Natural Death				1	
Survivors					
Terminal Sacrifice		25	25	25	25
Animals Examined Microscopically		25	25	26	25
ALIMENTARY SYSTEM					
Esophagus		(0)	(0)	(1)	(0)
Liver		(25)	(0)	(1)	(25)
Developmental Malformation		1			
Pancreas		(0)	(0)	(1)	(0)
CARDIOVASCULAR SYSTEM					
Blood Vessel		(0)	(0)	(1)	(0)
Heart		(0)	(0)	(1)	(0)
ENDOCRINE SYSTEM					
Adrenal Cortex		(25)	(0)	(2)	(25)
Adrenal Medulla		(25)	(0)	(2)	(25)
Pituitary Gland		(25)	(0)	(1)	(25)
Thyroid Gland		(25)	(0)	(1)	(25)
Bilateral, Keratin Cyst		1			
Keratin Cyst		1			1
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland		(3)	(0)	(0)	(0)

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: DOSED FEED

Species/Strain: Rat/CD

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014
Time Report Requested: 12:57:58

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number: 57-63-6** 

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

Lab: NCTR

CD Rat FEMALE	F4 CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Distended	3			
Inflammation, Chronic Active	3 [3.0]			
Ovary	(25)	(25)	(26)	(25)
Corpus Luteum, Cyst				1
Cyst	2	1		
Diestrus	6	7	9	8
Estrus	7	11	2	2
Follicle, Cyst	1			1
Metestrus	4	3	3	6
Proestrus	8	4	12	9
Oviduct	(25)	(25)	(26)	(25)
Uterus	(25)	(25)	(26)	(25)
Diestrus	5	6	7	7
Estrus	7	11	2	2
Metestrus	5	4	5	7
Proestrus	8	4	12	9
Vagina	(25)	(25)	(26)	(25)
Diestrus	5	6	7	7
Estrus	8	7	4	5
Metestrus	5	8	5	5
Proestrus	7	4	10	8
HEMATOPOIETIC SYSTEM				
Bone Marrow	(25)	(0)	(1)	(25)
Lymph Node	(0)	(0)	(1)	(0)
Lymph Node, Mandibular	(0)	(0)	(1)	(0)
Spleen	(25)	(0)	(2)	(25)
Thymus	(25)	(0)	(1)	(25)

INTEGUMENTARY SYSTEM

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: DOSED FEED

Species/Strain: Rat/CD

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 12:57:58

**Test Compound:** ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

**CAS Number: 57-63-6** 

Time Report Requested: 12:57:58

First Dose M/F: NA / NA

CD Rat FEMALE	F4 CONTROL	F4/2PPB TO CTRL	F4/10PPB TO CTRL	F4/50PPB TO CTRL
Mammary Gland	(25)	(25)	(26)	(25)
Alveolus, Hyperplasia	11 [1.7]	14 [1.4]	7 [1.1]	9 [1.4]
Lobules, Hyperplasia	4 [1.0]	10 [1.3]	2 [1.5]	4 [1.3]
Skin	(0)	(0)	(1)	(0)
MUSCULOSKELETAL SYSTEM				
Bone	(25)	(0)	(1)	(25)
NERVOUS SYSTEM				
Brain	(0)	(0)	(1)	(0)
RESPIRATORY SYSTEM				
Lung	(0)	(0)	(1)	(0)
Trachea	(0)	(0)	(1)	(0)
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(25)	(25)	(26)	(25)
Cortex, Cyst	2			2
Cyst			1	
Nephropathy		1 [1.0]	1 [1.0]	2 [1.0]
Renal Tubule, Mineralization	24 [1.5]	19 [1.3]	19 [1.7]	19 [1.3]

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

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)