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: 10:31:20

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: 10:31:20

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:20

First Dose M/F: NA / NA

CD Rat MALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPB
Disposition Summary				
Animals Initially In Study	25	25	25	26
Early Deaths				
Natural Death	1			1
Survivors				
Terminal Sacrifice	24	25	25	25
Animals Examined Microscopically	25	25	25	26
ALIMENTARY SYSTEM				
Esophagus	(1)	(0)	(0)	(1)
Liver	(24)	(1)	(2)	(25)
Basophilic Focus				1
Developmental Malformation		1		
Hepatodiaphragmatic Nodule	1		2	
Infiltration Cellular, Lymphocyte	6 [1.0]			8 [1.0]
Inflammation, Chronic Active	3 [1.0]			4 [1.0]
Pancreas	(1)	(0)	(0)	(0)
Acinus, Degeneration	1 [1.0]			
CARDIOVASCULAR SYSTEM				
Blood Vessel	(1)	(0)	(0)	(1)
Heart	(1)	(0)	(0)	(1)
ENDOCRINE SYSTEM				
Adrenal Cortex	(24)	(0)	(0)	(26)
Vacuolization Cytoplasmic	1 [1.0]			
Adrenal Medulla	(23)	(0)	(0)	(26)
Pituitary Gland	(24)	(0)	(0)	(25)
Pars Distalis, Cyst				2
Thyroid Gland	(24)	(0)	(0)	(25)

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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

CD Rat MALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PP
Cyst, Squamous	4			3
Cyst, Squamous, Multiple				1
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Coagulating Gland	(24)	(25)	(25)	(24)
Bilateral, Developmental Malformation	3	1		
Developmental Malformation	7	7	8	8
Epididymis	(25)	(25)	(25)	(26)
Atrophy	1 [4.0]			
Hypospermia	1 [4.0]			
Infiltration Cellular, Lymphocyte	2 [1.0]	3 [1.0]		1 [1.0]
Preputial Gland	(0)	(2)	(3)	(2)
Duct, Dilatation		1 [2.0]	2 [1.5]	1 [2.0]
Infiltration Cellular, Lymphocyte			1 [1.0]	
Inflammation, Suppurative		2 [1.5]	2 [4.0]	1 [4.0]
Prostate, Dorsal/Lateral Lobe	(5)	(5)	(8)	(9)
Infiltration Cellular, Lymphocyte	3 [1.3]	1 [2.0]	4 [1.0]	1 [1.0]
Inflammation, Suppurative	2 [1.5]	4 [1.5]	4 [1.5]	8 [1.8]
Prostate, Dorsal/lateral Lobe	(19)	(20)	(17)	(17)
Prostate, Ventral Lobe	(24)	(25)	(25)	(26)
Infiltration Cellular, Lymphocyte	20 [1.5]	18 [1.6]	19 [1.5]	21 [1.6]
Rete Testes	(25)	(23)	(24)	(25)
Dilatation	1 [3.0]	1 [2.0]	1 [4.0]	
Seminal Vesicle	(24)	(25)	(25)	(25)
Depletion Secretory	3 [3.3]	2 [2.5]	1 [4.0]	2 [4.0]
Testes	(25)	(25)	(25)	(26)
Seminif Tub, Degeneration	6 [1.7]	2 [2.0]	6 [1.8]	1 [1.0]

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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

Lab: NCTR

CD Rat MALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPE
HEMATOPOIETIC SYSTEM				
Bone Marrow	(24)	(0)	(0)	(25)
Spleen	(24)	(0)	(0)	(25)
Hyperplasia, Lymphoid	1 [1.0]			1 [1.0]
Pigmentation	2 [1.5]			7 [1.0]
Thymus	(24)	(0)	(0)	(25)
INTEGUMENTARY SYSTEM				
Mammary Gland	(24)	(24)	(25)	(25)
Alveolus, Dilatation			1 [2.0]	
Alveolus, Hyperplasia	1 [1.0]	2 [2.0]	5 [2.2]	10 [1.8]
Duct, Hyperplasia	2 [1.0]	1 [1.0]	2 [1.0]	2 [1.0]
Skin	(1)	(1)	(0)	(1)
Epidermis, Hyperplasia		1 [2.0]		
Hyperkeratosis		1 [1.0]		
MUSCULOSKELETAL SYSTEM				
Bone	(25)	(0)	(0)	(26)
NERVOUS SYSTEM				
Brain	(1)	(0)	(0)	(1)
Spinal Cord	(1)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(1)	(0)	(0)	(1)
Trachea	(0)	(0)	(0)	(1)
SPECIAL SENSES SYSTEM				
Eye	(1)	(0)	(0)	(0)
Autolysis	1 [4.0]			

URINARY 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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

CD Rat MALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPB
Kidney	(24)	(4)	(0)	(25)
Cortex, Cyst	4	1		4
Hyaline Droplet	2 [1.0]			6 [1.2]
Infiltration Cellular, Lymphocyte	17 [1.2]	2 [2.0]		19 [1.2]
Interstitium, Fibrosis	2 [1.0]	1 [2.0]		1 [2.0]
Pelvis, Dilatation				1 [1.0]
Renal Tubule, Degeneration	2 [1.0]	2 [1.5]		3 [1.0]
Renal Tubule, Dilatation	6 [1.7]	1 [4.0]		9 [1.3]
Renal Tubule, Mineralization	1 [1.0]			1 [1.0]
Renal Tubule, Regeneration	10 [1.0]	2 [1.0]		12 [1.1]
Urinary Bladder	(1)	(0)	(0)	(1)

^{***}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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

CD Rat FEMALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPB
Disposition Summary				
Animals Initially In Study	25	25	25	25
Early Deaths				
Survivors				
Terminal Sacrifice	25	25	25	25
Animals Examined Microscopically	25	25	25	25
ALIMENTARY SYSTEM				
Liver	(25)	(2)	(2)	(25)
Developmental Malformation	3	1	2	
Fatty Change, Focal	1 [2.0]			
Hepatodiaphragmatic Nodule		1		
Inflammation, Chronic Active	4 [1.0]			3 [1.0]
CARDIOVASCULAR SYSTEM None				
ENDOCRINE SYSTEM				
Adrenal Cortex	(25)	(0)	(0)	(25)
Accessory Adrenal Cortical Nodule	1			
Unilateral, Accessory Adrenal Cortical Nodule				1
Adrenal Medulla	(25)	(0)	(0)	(25)
Pituitary Gland	(25)	(0)	(0)	(25)
Cyst	1			
Thyroid Gland	(25)	(0)	(0)	(25)
GENERAL BODY SYSTEM None				
GENITAL SYSTEM				
Clitoral Gland	(2)	(1)	(2)	(0)
Omoral Glariu	(2)	(1)	(4)	(0)

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

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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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

CD Rat FEMALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPB
Distended	2	1	2	
Inflammation, Chronic Active	2 [3.0]	1 [4.0]		
Ovary	(25)	(25)	(25)	(25)
Corpus Luteum, Cyst	1	1		
Corpus Luteum, Depletion				1 [3.0]
Cyst		1	1	
Diestrus	7	6	8	6
Estrus	8	8	6	11
Follicle, Cyst			1	
Follicle, Cyst, Multiple				1
Metestrus	4	4	3	1
Proestrus	6	7	8	6
Oviduct	(24)	(25)	(25)	(25)
Mucosa, Hyperplasia		1 [2.0]		
Uterus	(25)	(25)	(25)	(25)
Diestrus	7	7	9	5
Endometrial GI, Dilatation		1 [3.0]		
Endometrial GI, Hyperplasia			1 [1.0]	
Estrus	7	7	6	12
Metestrus	4	4	3	1
Proestrus	7	7	7	7
Vagina	(25)	(25)	(25)	(25)
Diestrus	6	5	6	6
Epithelium, Hyperplasia				1 [2.0]
Estrus	6	8	6	9
Metestrus	7	5	3	4
Proestrus	6	7	10	5
EMATOPOIETIC SYSTEM				
Bone Marrow	(25)	(0)	(0)	(25)
	` '	` '	• •	` '

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: 99920-99 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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

CD Rat FEMALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPE
Spleen	(25)	(0)	(0)	(25)
Fibrosis, Focal	1 [1.0]			
Pigmentation	3 [1.0]			6 [1.5]
Thymus	(25)	(0)	(0)	(25)
INTEGUMENTARY SYSTEM				
Mammary Gland	(25)	(25)	(25)	(25)
Alveolus, Hyperplasia	1 [1.0]	4 [1.3]	3 [1.0]	4 [1.0]
Skin	(2)	(3)	(1)	(0)
Hyperkeratosis, Focal		1 [3.0]		
Inflammation, Chronic, Focal	1 [3.0]			
MUSCULOSKELETAL SYSTEM				
Bone	(25)	(0)	(0)	(25)
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(25)	(25)	(25)	(25)
Arteriole, Nuclear Alteration	, ,	. ,	` ,	1 [3.0]
Cortex, Cyst	3	3		
Infarct	1	1	1	
Inflammation, Chronic Active		1 [1.0]		
Nephropathy	2 [1.0]			3 [1.0]
Renal Tubule, Degeneration, Focal		1 [4.0]		
Renal Tubule, Dilatation, Focal			2 [2.0]	

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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: 10:31:21

Test Compound: ENDOCRINE DISRUPTOR(Ethinyl Estradiol)

CAS Number: 57-63-6

Time Report Requested: 10:31:21

First Dose M/F: NA / NA

Lab: NCTR

CD Rat FEMALE	F0 CONTROL	F0 2.0 PPB	F0 10 PPB	F0 50 PPB
Renal Tubule, Mineralization	20 [1.8]	22 [1.6]	24 [1.2]	17 [1.5]

** 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)