C Number:	MOG002B
Study Gender:	Both
PWG Approval Date	See web page for date of PWG Approval

F1 Male : Prenatal Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**23**	**20**	**22**	**20**	**15**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (PND 111 - 113)	**23**	**20**	**22**	**20**	**15**
Number of Animals Examined				**2**	
Total number litters				**2**	
ALIMENTARY SYSTEM					
None					
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
None					
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					

F1 Male : Prenatal Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

F1 Female : Prenatal Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**22**	**20**	**22**	**20**	**15**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (GD 20 - 21, PND 109 - 123)	**22**	**20**	**22**	**20**	**15**
Number of Animals Examined					
ALIMENTARY SYSTEM					
None					
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
None					
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					

F1 Female : Prenatal Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

F1 Male : Fertility Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**41**	**40**	**40**	**40**	**30**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (PND 153 - 155)	**41**	**40**	**40**	**40**	**30**
Number of Animals Examined	**41**	**40**	**40**	**40**	**30**
Total number litters	**22**	**20**	**21**	**20**	**15**
ALIMENTARY SYSTEM					
LIVER	(41)	(40)	(40)	(40)	(2)
HEPATODIAPHRAGMATIC NODULE			1 (2.5%) [1]	1 (2.5%) [1]	1 (50%) [1]
INFLAMMATION; FOCAL	3 (7.3%) [3]	10 (25%) [9] *	8 (20%) [8]	3 (7.5%) [3]	
HEPATOCYTE; NECROSIS; FOCAL	1 (2.4%) [1]				
MESENTERY	(0)	(0)	(0)	(1)	(0)
FAT; NECROSIS				1 (100%) [1]	
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
ADRENAL GLANDS	(41)	(0)	(0)	(40)	(0)
CORTEX; VACUOLATION; DIFFUSE				3 (7.5%) [3]	
PITUITARY GLAND	(41)	(0)	(0)	(40)	(0)
RATHKES CLEFT; CYST; MULTILOCULAR	1 (2.4%) [1]				
THYROID GLANDS	(41)	(0)	(0)	(40)	(30)
FOLLICULAR CELL; HYPERTROPHY; DIFFUSE	1 (2.4%) [1]				

F1 Male : Fertility Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
GENERAL BODY SYSTEM					
FAT	(0)	(0)	(0)	(0)	(1)
INFLAMMATION; CHRONIC ACTIVE					1 (100%) [1]
NECROSIS					1 (100%) [1]
GENITAL SYSTEM					
EPIDIDYMIDES	(41)	(0)	(1)	(40)	(30)
LUMEN; GERM CELL; EXFOLIATED (TOTAL)			1 (100%) [1]	1 (2.5%) [1]	
LUMEN; HYPOSPERMIA (TOTAL)			1 (100%) [1]	1 (2.5%) [1]	
PREPUTIAL GLANDS	(41)	(5)	(4)	(40)	(5)
DUCT; ECTASIA	23 (56.1%) [18]	4 (80%) [3]	4 (100%) [4]	32 (80%) [19] *	5 (100%) [4]
DUCT; FOREIGN MATERIAL					1 (20%) [1]
INFLAMMATION; CHRONIC ACTIVE	12 (29.3%) [9]	3 (60%) [2]	3 (75%) [3]	18 (45%) [14]	1 (20%) [1]
PROSTATE	(0)	(0)	(0)	(0)	(3)
INFILTRATION CELLULAR; MONONUCLEAR CELL					3 (100%) [3]
TESTES	(41)	(0)	(1)	(40)	(30)
GERMINAL EPITHELIUM; UNILATERAL; ATROPHY	2 (4.9%) [2]			1 (2.5%) [1]	
GERM CELL; DEGENERATION (TOTAL)	2 (4.9%) [2]		1 (100%) [1]	1 (2.5%) [1]	
VENTRAL PROSTATE	(41)	(0)	(0)	(40)	(27)
INTERSTITIUM; LYMPHOCYTE; INFILTRATION CELLULAR	8 (19.5%) [6]			6 (15%) [5]	
HEMATOLYMPHOID SYSTEM					
SPLEEN	(2)	(1)	(0)	(0)	(0)
CONGESTION		1 (100%) [1]			

F1 Male : Fertility Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
INTEGUMENTARY SYSTEM					
SKIN	(0)	(0)	(1)	(1)	(0)
HAIR FOLLICLE; ATROPHY; FOCAL				1 (100%) [1]	
EPIDERMIS; HYPERKERATOSIS; FOCAL				1 (100%) [1]	
EPIDERMIS; HYPERPLASIA; FOCAL				1 (100%) [1]	
DERMIS; INFLAMMATION; CHRONIC ACTIVE (TOTAL)			1 (100%) [1]	1 (100%) [1]	
EPIDERMIS; ULCERATION; FOCAL			1 (100%) [1]		
MUSCULOSKELETAL SYSTEM					
BONE	(2)	(0)	(1)	(0)	(0)
DEFORMITY			1 (100%) [1]		
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					

F1 Male : Fertility Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
URINARY SYSTEM					
KIDNEYS	(41)	(40)	(40)	(40)	(0)
CHRONIC PROGRESSIVE NEPHROPATHY	40 (97.6%) [22]	40 (100%) [20]	39 (97.5%) [21]	39 (97.5%) [20]	
PELVIS; CONCRETION	0 **			17 (42.5%) [13] **	
RENAL TUBULE; CONCRETION	0 **			35 (87.5%) [19] **	
UROTHELIUM; CONCRETION				1 (2.5%) [1]	
RENAL TUBULE; CYST			1 (2.5%) [1]		
PELVIS; RIGHT; DILATION	3 (7.3%) [3]		2 (5%) [2]	5 (12.5%) [5]	
RENAL TUBULE; DILATION	0 **			37 (92.5%) [20] **	
UROTHELIUM; HYPERPLASIA (TOTAL)	0 **	1 (2.5%) [1]		18 (45%) [15] **	
INFARCT	1 (2.4%) [1]				
INTERSTITIUM; INFLAMMATION; CHRONIC ACTIVE	0 **			22 (55%) [14] **	
MEDULLA; INFLAMMATION; GRANULOMATOUS	1 (2.4%) [1]				
PAPILLA; NECROSIS	0 **			10 (25%) [10] **	
UROTHELIUM; NECROSIS				1 (2.5%) [1]	
NEPHROBLASTEMATOSIS; FOCAL	1 (2.4%) [1]				
RENAL TUBULE; EPITHELIUM; REGENERATION	0 **			33 (82.5%) [17] **	
UROTHELIUM; ULCER	0 **			12 (30%) [9] **	
URINARY BLADDER	(2)	(0)	(0)	(17)	(0)
CONCRETION				11 (64.7%) [8]	
UROTHELIUM; EROSION; FOCAL				2 (11.8%) [2]	
UROTHELIUM; HYPERPLASIA; DIFFUSE				1 (5.9%) [1]	
SUBMUCOSA; INFLAMMATION; CHRONIC ACTIVE				1 (5.9%) [1]	

F1 Female : Fertility Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**41**	**40**	**40**	**40**	**30**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (GD 24, LD 28, PND 127 - 143)	**41**	**40**	**40**	**40**	**30**
Number of Animals Examined	**35**	**37**	**33**	**32**	**28**
Total number litters	**22**	**20**	**20**	**20**	**15**
ALIMENTARY SYSTEM					
LIVER	(35)	(2)	(1)	(32)	(0)
HEPATODIAPHRAGMATIC NODULE		2 (100%) [2]	1 (100%) [1]	4 (12.5%) [3]	
INFLAMMATION; FOCAL				2 (6.3%) [2]	
MESENTERY	(0)	(1)	(0)	(0)	(0)
FAT; NECROSIS		1 (100%) [1]			
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
ADRENAL GLANDS	(35)	(0)	(1)	(32)	(0)
UNILATERAL; CONGESTION; DIFFUSE			1 (100%) [1]		
CORTEX; HYPERTROPHY; FOCAL	1 (2.9%) [1]				
CORTEX; VACUOLATION; DIFFUSE				2 (6.3%) [2]	
PITUITARY GLAND	(35)	(0)	(0)	(32)	(0)
PARS DISTALIS; CYST	1 (2.9%) [1]				
THYROID GLANDS	(35)	(0)	(0)	(32)	(28)
FOLLICULAR CELL; HYPERTROPHY; DIFFUSE	1 (2.9%) [1]				

F1 Female : Fertility Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
CLITORAL GLANDS	(3)	(1)	(1)	(0)	(1)
DUCT; ECTASIA (TOTAL)	3 (100%) [3]	1 (100%) [1]	1 (100%) [1]		1 (100%) [1]
INFLAMMATION, CHRONIC; ACTIVE	1 (33.3%) [1]				
OVARIES	(35)	(1)	(0)	(32)	(28)
CORPUS LUTEUM; CYST	3 (8.6%) [3]			2 (6.3%) [2]	1 (3.6%) [1]
FOLLICLE; CYST	3 (8.6%) [3]				
PERIOVARIAN; FAT; NECROSIS		1 (100%) [1]			
UTERUS	(35)	(0)	(0)	(32)	(0)
MUCOSA; DECIDUAL ALTERATION; FOCAL	1 (2.9%) [1]				
ENDOMETRIUM; HYPERPLASIA; CYSTIC	2 (5.7%) [2]				
VAGINA	(33)	(0)	(0)	(32)	(0)
EPITHELIUM; CYST	1 (3%) [1]			1 (3.1%) [1]	
HEMATOLYMPHOID SYSTEM					
LYMPH NODE, MANDIBULAR	(0)	(0)	(0)	(1)	(0)
CONGESTION				1 (100%) [1]	
LYMPHOCYTE; DEPLETION				1 (100%) [1]	
SPLEEN	(2)	(0)	(0)	(0)	(0)
RED PULP; PIGMENTED MACROPHAGE; INCREASED	1 (50%) [1]				
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					

F1 Female : Fertility Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					

F1 Female : Fertility Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
URINARY SYSTEM					
KIDNEYS	(35)	(37)	(33)	(32)	(0)
CHRONIC PROGRESSIVE NEPHROPATHY	18 (51.4%) [14]	35 (94.6%) [19] **	29 (87.9%) [19] **	22 (68.8%) [17]	
PELVIS; CONCRETION	0 **			9 (28.1%) [5]	
RENAL TUBULE; CONCRETION	0 **			13 (40.6%) [12] **	
RENAL TUBULE; CYST			3 (9.1%) [3]	1 (3.1%) [1]	
RENAL TUBULE; EPITHELIUM; DEGENERATION	0 **			21 (65.6%) [14] **	
PELVIS; DILATION (TOTAL)	0 *	1 (2.7%) [1]		5 (15.6%) [5]	
RENAL TUBULE; DILATION	0 **			28 (87.5%) [19] **	
CAPSULE; FIBROSIS				1 (3.1%) [1]	
UROTHELIUM; HYPERPLASIA; DIFFUSE	0 **			15 (46.9%) [12] **	
INTERSTITIUM; INFLAMMATION; CHRONIC ACTIVE	0 **			8 (25%) [8] *	
UROTHELIUM; METAPLASIA; SQUAMOUS				1 (3.1%) [1]	
MINERALIZATION	9 (25.7%) [8]	28 (75.7%) [17] **	24 (72.7%) [18] **	10 (31.3%) [8]	
PAPILLA; NECROSIS	0 *			4 (12.5%) [3]	
NEPHROBLASTEMATOSIS; FOCAL		2 (5.4%) [2]			
RENAL TUBULE; EPITHELIUM; REGENERATION	0 **		3 (9.1%) [3]	13 (40.6%) [12] **	
UROTHELIUM; ULCER	0 **			6 (18.8%) [6] *	
URETERS	(1)	(0)	(0)	(1)	(0)
UROTHELIUM; HYPERPLASIA; DIFFUSE				1 (100%) [1]	
URINARY BLADDER	(0)	(0)	(0)	(1)	(0)
CONCRETION				1 (100%) [1]	
LUMEN; DILATION				1 (100%) [1]	
UROTHELIUM; HYPERPLASIA; FOCAL				1 (100%) [1]	

F2 Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**91**	**110**	**101**	**88**	**87**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (PND 28)	**91**	**110**	**101**	**88**	**87**
Number of Animals Examined				**3**	**1**
Total number litters				**3**	**1**
ALIMENTARY SYSTEM					
None					
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
None					
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					

F2 Male

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

F2 Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
Disposition Summary					
Animals Initially In Study	**94**	**95**	**85**	**86**	**91**
Early Deaths					
Scheduled Deaths					
Scheduled sacrifice, terminal (PND 28)	**94**	**95**	**85**	**86**	**91**
Number of Animals Examined	**1**	**1**			
Total number litters	**1**	**1**			
ALIMENTARY SYSTEM					
None					
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
None					
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					

F2 Female

	Treatment Groups (ppm)				
	0	**3000**	**10000**	**30000**	**0.05 ppm EE**
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

LEGEND

Number of animals examined for each tissue shown in parentheses. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number of animals with observation reported with percent incidence in parentheses

Number of litters with observations shown in square brackets for F1 and F2 animals. F1 litter incidence based on the number of F0 dams; F2 litter incidence based on number of F1 dams.

All trend and pairwise p-values are reported as one-sided.

Trend p-values are reported only for those organs that were fully examined in the control group plus two or more other dose groups. For organs that were fully examined in just the control and one other dose group, only the pairwise p-values are reported.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

* Statistically significant at P <= 0.05

** Statistically significant at P <= 0.01

Lesions in the F1 generation animals were analyzed using a Cochran-Armitage test with a poly-3 adjustment for age and a Rao-Scott modification for the random effect due to litter.

Lesions in the F2 animals were analyzed using a Cochran-Armitage test with a Rao-Scott modification for the random effect due to litter.

EE = Ethinyl estradiol

** END OF REPORT **