C Number:	MOG003B
Study Gender:	Both
PWG Approval Date	See web page for date of PWG Approval

F0 Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**26**	**26**	**26**	**26**
Early Deaths				
Unscheduled Sacrifice	**1**			**1**
Scheduled Deaths				
Scheduled sacrifice, terminal (LD 28, SD 24 - 27)	**25**	**26**	**26**	**25**
Number of Animals Examined	**3**		**1**	**1**
ALIMENTARY SYSTEM				
LIVER	(3)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				

F0 Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYES	(0)	(0)	(0)	(1)
URINARY SYSTEM				
None				

F1 Male : Subchronic Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**10**	**10**	**10**	**10**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 110 - 112)	**10**	**10**	**10**	**10**
Number of Animals Examined	**10**	**1**	**2**	**10**
Total number litters	**10**	**1**	**2**	**10**
ALIMENTARY SYSTEM				
INTESTINE, ILEUM	(10)	(0)	(0)	(10)
LIVER	(10)	(0)	(1)	(10)
STOMACH, FORESTOMACH	(10)	(0)	(0)	(10)
STOMACH, GLANDULAR	(10)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM				
HEART	(10)	(0)	(0)	(10)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(10)	(0)	(0)	(10)
THYROID GLANDS	(10)	(0)	(0)	(10)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
EPIDIDYMIDES	(10)	(1)	(0)	(10)
PREPUTIAL GLANDS	(10)	(0)	(0)	(10)
TESTES	(10)	(1)	(0)	(10)
VENTRAL PROSTATE	(10)	(0)	(0)	(10)

F1 Male : Subchronic Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
HEMATOLYMPHOID SYSTEM				
THYMUS	(10)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNG	(10)	(0)	(0)	(10)
NOSE	(0)	(0)	(0)	(1)
TRACHEA	(10)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEYS	(10)	(0)	(1)	(10)

F1 Female : Subchronic Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**10**	**10**	**10**	**10**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 111 - 113)	**10**	**10**	**10**	**10**
Number of Animals Examined	**10**	**3**	**3**	**10**
Total number litters	**10**	**3**	**3**	**10**
ALIMENTARY SYSTEM				
LIVER	(10)	(0)	(1)	(10)
SALIVARY GLANDS	(10)	(1)	(0)	(10)
PAROTID; ADENOCARCINOMA		1 (100%) [1]		
STOMACH, GLANDULAR	(10)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM				
HEART	(10)	(0)	(0)	(10)
ENDOCRINE SYSTEM				
PITUITARY GLAND	(10)	(0)	(0)	(10)
THYROID GLANDS	(10)	(0)	(0)	(10)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
CLITORAL GLANDS	(10)	(2)	(2)	(10)
OVARIES	(10)	(0)	(0)	(10)
UTERUS	(10)	(0)	(0)	(10)

F1 Female : Subchronic Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
HEMATOLYMPHOID SYSTEM				
SPLEEN	(10)	(0)	(0)	(10)
HISTIOCYTIC SARCOMA				1 (10%) [1]
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNG	(10)	(0)	(0)	(10)
NOSE	(1)	(0)	(0)	(0)
TRACHEA	(10)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM				
ZYMBALS GLANDS	(10)	(0)	(0)	(9)
URINARY SYSTEM				
KIDNEYS	(10)	(0)	(0)	(10)

F1 Male : Prenatal Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**21**	**23**	**20**	**22**
Early Deaths				
Unscheduled Sacrifice			**1**	
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 112 - 114)	**21**	**23**	**19**	**22**
Number of Animals Examined	**5**	**3**	**2**	**2**
Total number litters	**5**	**3**	**2**	**2**
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(2)	(2)	(0)	(0)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				

F1 Male : Prenatal Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEYS	(3)	(1)	(2)	(1)

F1 Female : Prenatal Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**21**	**23**	**19**	**22**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (GD 21, PND 109 - 132)	**21**	**23**	**19**	**22**
Number of Animals Examined	**3**		**1**	**1**
Total number litters	**3**		**1**	**1**
ALIMENTARY SYSTEM				
LIVER	(3)	(0)	(1)	(0)
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	**1000**	**3000**	**6000**
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
None				

F1 Male : Fertility Males

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**36**	**46**	**35**	**37**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 160 - 167)	**36**	**46**	**35**	**37**
Number of Animals Examined	**36**	**46**	**35**	**37**
Total number litters	**21**	**24**	**19**	**22**
ALIMENTARY SYSTEM				
ESOPHAGUS	(3)	(0)	(0)	(0)
INTESTINE, COLON	(3)	(0)	(0)	(0)
LIVER	(3)	(2)	(1)	(1)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(36)	(0)	(0)	(37)
ADRENAL MEDULLA	(36)	(0)	(0)	(37)
PITUITARY GLAND	(36)	(0)	(0)	(37)
THYROID GLANDS	(36)	(0)	(0)	(37)
GENERAL BODY SYSTEM				
None				

F1 Male : Fertility Males

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
GENITAL SYSTEM				
COWPERS GLANDS	(36)	(2)	(0)	(37)
DORSAL PROSTATE	(36)	(46)	(35)	(37)
EPIDIDYMIDES	(36)	(46)	(35)	(37)
PREPUTIAL GLANDS	(36)	(6)	(2)	(37)
TESTES	(36)	(46)	(35)	(37)
VENTRAL PROSTATE	(36)	(46)	(35)	(37)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
SKIN	(0)	(1)	(0)	(0)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNG	(3)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEYS	(3)	(1)	(2)	(0)

F1 Female : Fertility Females

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**36**	**46**	**35**	**38**
Early Deaths				
Euthanized, moribund				**1**
Unscheduled Sacrifice			**1**	
Scheduled Deaths				
Scheduled sacrifice, terminal (GD 44 - 49, LD 14 - 28, PND 151 - 154)	**36**	**46**	**34**	**37**
Number of Animals Examined	**32**	**5**	**2**	**25**
Total number litters	**19**	**5**	**2**	**19**
ALIMENTARY SYSTEM				
LIVER	(4)	(0)	(0)	(1)
CARDIOVASCULAR SYSTEM				
HEART	(2)	(0)	(1)	(0)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(26)	(0)	(0)	(23)
PITUITARY GLAND	(26)	(0)	(0)	(23)
THYROID GLANDS	(26)	(0)	(0)	(23)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
CLITORAL GLANDS	(2)	(1)	(1)	(0)
OVARIES	(26)	(0)	(0)	(23)
UTERUS	(26)	(3)	(0)	(23)

F1 Female : Fertility Females

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(2)	(1)	(0)	(0)
ADENOCARCINOMA		1 (100%) [1]		
SKIN	(2)	(0)	(0)	(1)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEYS	(2)	(0)	(0)	(1)

F2 Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**94**	**135**	**86**	**96**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 28)	**94**	**135**	**86**	**96**
Number of Animals Examined	**8**	**3**	**2**	**6**
Total number litters	**5**	**3**	**2**	**5**
ALIMENTARY SYSTEM				
LIVER	(2)	(2)	(0)	(3)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
TESTES	(4)	(1)	(2)	(1)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(0)	(1)
MUSCULOSKELETAL SYSTEM				
None				

F2 Male

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
None				

F2 Female

	Treatment Groups (ppm)			
	0	**1000**	**3000**	**6000**
Disposition Summary				
Animals Initially In Study	**110**	**125**	**85**	**102**
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 28)	**110**	**125**	**85**	**102**
Number of Animals Examined	**2**		**1**	**1**
Total number litters	**1**		**1**	**1**
ALIMENTARY SYSTEM				
LIVER	(2)	(0)	(1)	(1)
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	**1000**	**3000**	**6000**
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.

Trend significance is 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 significance is reported.

Statistical analysis of the F1 Subchronic cohort was performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

Statistical analysis for the F1 Fertility animals was performed by Cochran-Armitage test with a poly-3 adjustment for age and a Rao-Scott modification for the random effect due to litter.

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

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

Non-pregnant females from the F0 and F1 generations are included in the analysis.

SD – Study Day; GD – Gestation Day; LD – Lactation Day; PND – Postnatal Day, adults post-weaning

** END OF REPORT **