C Number:	C11054-02
Study Gender:	Both
PWG Approval Date	See web page for date of PWG Approval

Male

	Treatment Groups (mg/kg)						
	0	**1**	**10**	**30**	**100**	**300**	**800**
Disposition Summary							
Animals Initially In Study	**16**	**13**	**13**	**16**	**16**	**16**	**13**
Scheduled sacrifice, interim							**7**
Early Deaths							
Found Dead							**6**
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 28 - 29)	**16**	**13**	**13**	**16**	**16**	**16**	
Number of Animals Examined	**10**	**10**	**10**	**10**	**10**	**10**	**11**
ALIMENTARY SYSTEM							
LIVER	(10)	(0)	(0)	(0)	(0)	(10)	(11)
EXTRAMEDULLARY HEMATOPOEISIS							1 (9.1%)
INFLAMMATION; CHRONIC-ACTIVE						1 (10%)	
STOMACH, FORESTOMACH	(10)	(0)	(0)	(0)	(0)	(10)	(11)
HYPERKERATOSIS							2 (18.2%)
STOMACH, GLANDULAR	(10)	(0)	(0)	(10)	(10)	(10)	(11)
CHIEF CELL; HYPERPLASIA	0 **				1 (10%)	3 (30%)	7 (63.6%) **
LIMITING RIDGE; METAPLASIA; SQUAMOUS						1 (10%)	
MINERAL	0 **				1 (10%)	2 (20%)	7 (63.6%) **
CARDIOVASCULAR SYSTEM							
HEART	(10)	(0)	(0)	(0)	(0)	(10)	(11)
CARDIOMYOPATHY						1 (10%)	1 (9.1%)
ENDOCRINE SYSTEM							
None							
GENERAL BODY SYSTEM							
None							

Male

	Treatment Groups (mg/kg)						
	0	**1**	**10**	**30**	**100**	**300**	**800**
GENITAL SYSTEM							
PROSTATE GLAND	(10)	(0)	(0)	(0)	(0)	(10)	(11)
INFILTRATION, CELLULAR; MONONUCLEAR CELL						1 (10%)	
HEMATOPOIETIC SYSTEM							
SPLEEN	(10)	(10)	(10)	(10)	(10)	(10)	(11)
WHITE PULP; ATROPHY					2 (20%)		1 (9.1%)
INTEGUMENTARY SYSTEM							
None							
LYMPHOID SYSTEM							
None							
MUSCULOSKELETAL SYSTEM							
None							
NERVOUS SYSTEM							
None							
RESPIRATORY SYSTEM							
None							
SPECIAL SENSES SYSTEM							
None							
URINARY SYSTEM							
KIDNEY	(10)	(0)	(0)	(0)	(0)	(10)	(11)
NEPHROPATHY; CHRONIC-PROGRESSIVE	1 (10%)					1 (10%)	

Female

	Treatment Groups (mg/kg)						
	0	**1**	**10**	**30**	**100**	**300**	**800**
Disposition Summary							
Animals Initially In Study	**16**	**13**	**13**	**16**	**16**	**16**	**13**
Early Deaths							
Found Dead							**8**
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 18 - 29)	**16**	**13**	**13**	**16**	**16**	**16**	**5**
Number of Animals Examined	**10**	**10**	**10**	**10**	**10**	**10**	**11**
ALIMENTARY SYSTEM							
LIVER	(10)	(0)	(0)	(0)	(0)	(10)	(11)
EXTRAMEDULLARY HEMATOPOEISIS						2 (20%)	
INFLAMMATION; CHRONIC-ACTIVE	5 (50%)					4 (40%)	4 (36.4%)
STOMACH, GLANDULAR	(10)	(0)	(0)	(0)	(0)	(10)	(11)
MINERAL							2 (18.2%)
CARDIOVASCULAR SYSTEM							
None							
ENDOCRINE SYSTEM							
ISLETS, PANCREATIC	(1)	(0)	(0)	(0)	(0)	(1)	(0)
HYPERPLASIA	1 (100%)					1 (100%)	
GENERAL BODY SYSTEM							
None							
GENITAL SYSTEM							
CERVIX	(10)	(0)	(0)	(0)	(0)	(10)	(11)
INFLAMMATION; CHRONIC-ACTIVE	1 (10%)					1 (10%)	

Female

	Treatment Groups (mg/kg)						
	0	**1**	**10**	**30**	**100**	**300**	**800**
HEMATOPOIETIC SYSTEM							
THYMUS	(10)	(0)	(0)	(0)	(0)	(10)	(11)
AUTOLYSIS							1 (9.1%)
INTEGUMENTARY SYSTEM							
None							
LYMPHOID SYSTEM							
None							
MUSCULOSKELETAL SYSTEM							
None							
NERVOUS SYSTEM							
None							
RESPIRATORY SYSTEM							
None							
SPECIAL SENSES SYSTEM							
EYE	(10)	(0)	(0)	(1)	(0)	(10)	(11)
AUTOLYSIS							1 (9.1%)
URINARY SYSTEM							
KIDNEY	(10)	(0)	(0)	(0)	(0)	(10)	(11)
INFLAMMATION; CHRONIC-ACTIVE						1 (10%)	
NEPHROPATHY; CHRONIC-PROGRESSIVE	1 (10%)					2 (20%)	

LEGEND

Number of animals examined given for each tissue. 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 analysis is performed 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

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

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

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

* Statistically significant at P <= 0.05

** Statistically significant at P <= 0.01

All animals in the 800 mg/kg dose group either died or were removed by Study Day 20.

** END OF REPORT **