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Table 5 (Cont'd)  
Summary of Primary Neoplasms

TUMORS	NUMERIC INCIDENCE OF NEOPLASTIC LESIONS												
	MALES						FEMALES						
	GROUP	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	GROUP	
UROGENITAL SYSTEMS:- URINARY BLADDER:													
MYELOMONOCYTIC LEUKEMIA (M)	3												
TESTIS/EPIDIDYMIS:													
INTERSTITIAL CELL TUMOR (B)	3	5	5	4	7								
HISTIOCYTIC SARCOMA (H)	1			1									
PROSTATE:	(69)	(60)	(63)	(58)	(69)								
ADENOCARCINOMA (M), metastasizing	1				3								
LEUKEMIA (M), lymphoid				1									
EPIDIDYMAL VESICLES:	(69)	(59)	(61)	(58)	(69)								
HISTIOCYTIC SARCOMA (H)	1												
LEUKEMIA (M), lymphoid													
OVARY:													
GRANULOSA CELL TUMOR (B)													
LUTEOMA (B)													
THECOMA (B)													

Figures in parentheses represent the number of animals from which this tissue was examined.

The absence of a numeral indicates that the lesion specified was not identified  
(B) = benign, (H) = malignant

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Table 5 (Cont'd)  
Summary of Primary Neoplasms

TUMORS	NUMERIC INCIDENCE OF NEOPLASTIC LESIONS											
	MALES						FEMALES					
	GROUP	01	0.51	51	501	2001	01	0.51	51	501	2001	
		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	
UROGENITAL SYSTEMS-												
OVARY												
TUBULAR ADENOMA (B), papilloform						1						
TUBULAR ADENOMA (B), metastasizing, unilateral								1				
MESOTHELIOMA (M), metastasizing												
MALIGNANT LYMPHOMA, LYMPHOCTIC (M), bilateral												
LIPOMA (B), buccal												1
HISTIOCYTIC SARCOMA (M)												
UTERUS												
ENDOMETRIAL STROMAL POLYP (B)												
ENDOMETRIAL STROMAL SARCOMA (M)												
LEIOMYOSARCOMA (M)												
MALIGNANT LYMPHOMA, LYMPHOCTIC (M)												
HISTIOCYTIC SARCOMA (M)												

Figures in parentheses represent the number of animals from which this tissue was examined.

The absence of a numeral indicates that the lesion specified was not identified

(B) = benign, (M) = malignant

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PLACES VR.204

Table 5 (Cont'd)  
Summary of Primary Neoplasms

TUMORS	NUMERIC INCIDENCE OF NEOPLASTIC LESIONS											
	MALES						FEMALES					
	GROUP	01	0.51	51	501	2001	01	0.51	51	501	2001	GROUP
	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
ENDOCRINE SYSTEM:-												
PITUITARY:												
ADENOMA (B), pars distalis	(70)	(65)	(67)	(66)	(70)	(70)	(62)	(64)	(63)	(70)		
CARCINOMA (M), pars distalis												
ADENOMA (B), pars intermedia	1					1						
MALIGNANT LYMPHOMA, LYMPHOCTIC (M)												
ADRENAL:												
CORTICAL ADENOMA (B)	6	1	3		2	3				1		
CORTICAL CARCINOMA (M)					1		3	1	1	2		
PHEOCHROMOCYTOMA (B)	11	7	6	6	8	4				2		
PHEOCHROMOCYTOMA (M)	2	1				1						
HISTIOCYTIC SARCOMA (M)						1						
MYELOMONOCYTIC LEUKEMIA (M)						1						
THYROID:												
FOLLICULAR CELL ADENOMA (B)	(70)	(70)	(69)	(69)	(70)	(70)	(70)	(70)	(70)	(70)		
FOLLICULAR CELL CARCINOMA (M)	1	1	1	1	7	1				3		

Figures in parentheses represent the number of animals from which this tissue was examined.

The absence of a numeral indicates that the lesion specified was not identified (B) = benign, (M) = malignant

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Table 5 (Cont'd)  
Summary of Primary Neoplasms

TUMORS	NUMERIC INCIDENCE OF NEOPLASTIC LESIONS											
	MALES						FEMALES					
	0	0.5	1	50	100	200	0	0.5	1	50	100	200
GROUP	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
ENDOCRINE SYSTEM:-												
THYROID:												
C-CELL ADENOMA (B)	3	4	2	3	2		3	3	3	2	7	
C-CELL CARCINOMA (M)		1	3				1		1	2	1	
PARATHYROID:												
ADENOMA (B)	1	1	1	1	1		1	1	1	1	1	
NERVOUS SYSTEM:-												
BRAIN:												
NEUROBLASTOMA (M)												
ASTROCYTOMA (M)												
GRANULAR CELL TUMOR (B)												
MYELOXEROCYTIC LEUKEMIA (M)												
MALIGNANT LYMPHOMA, LYMPHOBLASTIC (M)												
HISTIOCYTIC SARCOMA (M)												

Figures in parentheses represent the number of animals from which this tissue was examined.

The absence of a numeral indicates that the lesion specified was not identified  
(B) = benign, (M) = malignant

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PLACES VB.204

Table 3 (Cont'd)  
Summary of Primary Neoplasms

TUMOR	NUMERIC INCIDENCE OF NEOPLASTIC LESIONS												
	GROUP	MALES						FEMALES					
		01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day		01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	
SPECIAL SENSE ORGANS - EYE, SQUAMOUS CELL CARCINOMA (M), periorbital, metastasizing HISTIOCYTIC SARCOMA (M) ESOPHAGUS, SQUAMOUS CELL CARCINOMA (M), metastasizing PAPILLOMA (B) SQUAMOUS CELL CARCINOMA (M)		(70)	(82)	(83)	(59)	(70)		(70)	(48)	(49)	(82)	(70)	

Figures in parentheses represent the number of animals from which this tissue was examined.

The absence of a numeral indicates that the lesion specified was not identified  
(B) = benign, (M) = malignant

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**APPENDIX 2B**

Sprague Dawley Rat Carcinogenicity Study, Histopathology  
Non-neoplastic Lesion Data.

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**APPEARS THIS WAY  
ON ORIGINAL**

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Table 6

Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0	0.5	1	5	50	100	0	0.5	1	5	50	100
GROUP	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
BODY AS A WHOLE:-												
THORACIC CAVITY:												
Arteritis, mixed, focal		(3)	(3)	(6)	(11)			(1)	(2)		(4)	
Vena cava; Thrombosis				1	3							
ABDOMINAL CAVITY:												
No abnormality detected	(3)	(1)	(1)	(4)	(5)			(1)	(4)		(2)	
INTEGUMENTARY SYSTEM:-												
SKIN:												
No abnormality detected	(70)	(64)	(62)	(66)	(70)			(70)	(55)	(46)	(70)	
Ulceration/dermatitis	49	47	54	40	48			60	43	41	36	59
Folliculitis, focal	6	3	1	2	1				1	1	1	
Grenuloma			1									
Abscess										1		1
Epidermal cyst				1	1	3				2		
Ectasia, duct											1	
Acanthosis	3								1		1	

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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PLACES VA. 204

Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0	0.5	1	5	50	200	0	0.5	1	5	50	200
GROUP	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
<b>INTESTINARY SYSTEM:</b>												
<b>BRIM:</b>												
Necrosis, tip of tail	(70)	(64)	(62)	(66)	(70)	(70)	(55)	(50)	(46)	(46)	(70)	
Dysplasia, follicular								1				
<b>PRIMARY GLAND:</b>												
No abnormality detected	(41)	(36)	(24)	(32)	(38)	(48)	(63)	(65)	(61)	(67)	(67)	
Epithelial proliferation, atypical	20	23	23	25	30	19	10	11	8	20	20	
Heartitis	1	1				3	3	2	2	1		
Gastrocels	2	2	1	1	1	2	2	4	1			
Ectasia, duct	7	4	1	3	2	4	3	4	2	4	4	
<b>PREPUTIAL GLAND:</b>												
Squamous cell hyperplasia, ductular	2			2	1		1					
Abcess	(4)	(5)	(3)	(7)								
Adenitis	3	3	2	4								
Ectasia, duct	3	5	2	5								

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS													
	MALES						FEMALES							
GROUP	01	0.31	51	50	2001	0	0.51	51	50	2001	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
INTEGUMENTARY SYSTEM:-														
CLITORAL GLAND:														
Adenitis														
Ectasia, duct														
HEMATOPOIETIC and LYMPHATIC SYSTEMS:-														
BONE MARROW:														
No abnormality detected	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)				
Hyperplasia	67	69	70	64	67	64	67	60	67	63				
minimal	1		2					3		3				
mild			2		2			3		2				
moderate										1				
Hypocellularity					1									
SPLEEN:														
No abnormality detected	(70)	(40)	(61)	(59)	(70)	(69)	(51)	(50)	(44)	(70)				
Infarct	54	54	51	48	65	46	32	28	23	50				
Hyperplasia, lymphoid	1			1	1		1			1				

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	01	0.51	51	501	2001		01	0.51	51	501	2001	
GROUP	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	
<b>HEMATOPOIETIC AND LYMPHATIC SYSTEMS:-</b>												
<b>SPLEEN:</b>	(70)	(40)	(61)	(59)	(70)		(69)	(51)	(50)	(44)	(70)	
Hemotoplasia, extramedullary	10	3	6	5	3		19	18	17	17	17	
Polyarteritis nodosa		1										
Medial degeneration, arteriolar				1								
Mononuclear cell infiltrate										1		
Cyst, NOS, acrosal								1				
Mineralisation, arteriolar	1	2	3	2			1			2		
Fibrosis	1		1	1	1							
Atrophy, follicular												
Hemosiderosis												
Ectasia, sinusoidal												
<b>THYROID:</b>	(55)	(54)	(47)	(35)	(57)		(50)	(42)	(44)	(39)	(60)	
No abnormality detected	49	39	40	30	49		30	19	20	15	34	
Epithelial cords/tubules	2	3	1	1	2		14	10	13	7	10	
Lymphoid hyperplasia								1	1			

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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PLACES VB.204

Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	GROUP	01	0.51	501	2001		01	0.51	501	2001		
	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day			
HEMATOPOIETIC and LYMPHATIC SYSTEMS:-												
THYRUS:	(55)	(54)	(47)	(35)	(57)	(50)	(43)	(44)	(29)	(60)		
Atrophy				1	1					2		
↑ Hemorrhage, acute	3	13	3	3	5	7	7	10	7	4		
↓ Cyst, NOS						1		1				
LYMPH NODE(S):	(2)			(3)	(1)	(1)		(1)		(1)		
Hyperplasia, lymphoid				1				1				
Hemorrhage, acute												
LYMPH NODE - MANDIBULAR:	(69)	(58)	(60)	(58)	(69)	(69)	(46)	(47)	(41)	(70)		
No abnormality detected	63	52	56	52	64	66	45	45	37	68		
Hyperplasia, lymphoid		2	2		1	1		2		1		
Lymphadenitis	1				1				1			
Hemorrhage, acute		2		1								
Erythrocytes in sinuses	2	2	2	2	1	2	1		3			
Hemoliderosis					1							

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	GROUP						SEXES					
	0	0.51	51	50	200	200	0	0.51	51	50	200	200
MUSCULOSKELETAL SYSTEM AND SOFT TISSUES:-												
SKELETAL MUSCLE:												
No abnormality detected	(70)	(61)	(62)	(58)	(70)	(70)	(70)	(48)	(49)	(42)	(70)	(70)
Polyarteritis nodosa	48	60	61	57	70	70	69	48	48	41	70	70
Arteritis, fibrinoid, focal	2						1					
Myositis, focal	1	1	1				1					
RESPIRATORY SYSTEM:-												
LARYNX:												
No abnormality detected	(70)	(61)	(61)	(58)	(70)	(70)	(70)	(48)	(49)	(42)	(70)	(70)
TRACHEA:												
No abnormality detected	62	56	51	49	61	61	67	40	46	60	65	65
Tracheitis	2	1	6	5	3	3	1					
Hyperplasia, epithelial												
Lumen filled with ingesta	1			1								
Intraluminal neutrophils			1									

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 5 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	01	0.51	51	501	2001		01	0.51	51	501	2001	
mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	(70)	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	(70)	
RESPIRATORY SYSTEM:-												
LUNG:												
No abnormality detected	49	37	33	34	34	(70)	52	35	36	26	43	(70)
Alveolitis	1	5	3	2	3		4	2	1	2	5	
Hyperplasia, alveolar, focal	1				2		1	3				
Alveolar histiocytosis	10	16	13	13	22		9	3	4	3	13	
Pneumonia, granulomatous	1				1							
Bronchopneumonia	1		2	1	2		1	1	3	1	1	
Bronchitis					1					1		
Pleuritis, mixed, multifocal										1		
Congestion, acute	2	6	3	2	5		2	2	1	3	4	
Edema	1				2		1				1	
Thrombosis	1		1		4							
Hemorrhage, acute, multifocal					2							2
Mineralization, alveolar	1	3	1				1	1			1	
Heteroplasia, osseous, focal					3						1	

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0 mg/kg /day	0.5 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day		0 mg/kg /day	0.5 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day	
RESPIRATORY SYSTEM:-												
LUNG:												
Hyperplasia, smooth muscle, focal												
Fragments of plant material in airways	1											
Intra-arteriolar bacterial clusters			1								1	
Leukemoid reaction												
CARDIOVASCULAR SYSTEM:-												
HEART:												
No abnormality detected	9	31	0	10	0		39	25	34	20	20	
Cardiomyopathy												
minimal	15	14	11	5	7		22	12	10	13	11	
mild	24	14	17	23	16		13	6	3	4	27	
moderate	31	10	10	16	16		4	3		2	0	
Thrombosis, atrial	3	7	6	5	6		1			2	4	
Thrombosis, valvular	1	1										
Myocardial mineralization	3	11	12	0	6		3	1	1	2	3	

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	MICROSCOPIC INCIDENCE OF MICROSCOPIC OBSERVATIONS															
	MALES						FEMALES									
	0	0.51	51	501	2001	GROUP	0	0.51	51	501	2001	GROUP				
	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
CARDIOVASCULAR SYSTEM- HEART	(70)	(61)	(61)	(58)	(70)		(70)	(49)	(49)	(42)	(70)		(70)	(49)	(42)	(70)
Mineralization, arterial/arteriolar	3	10	11	6	6		3	1	2	2	2		3	1	2	2
Epicarditis			1	1										1		
Myocarditis, atrial, mixed																
Necrosis, myocardial, atrial					1											
Myointimal proliferation with medial degeneration, arteriolar				1	3											
Fibrinoid necrosis, arteriolar, focal				1												
Arteritis, necrotizing, coronary arterial, focal					1											
Subendocardial fibrosis				1												1
Metaplasia, cartilaginous, focal	1			1												
AORTA	(70)	(61)	(58)	(55)	(59)		(70)	(48)	(49)	(40)	(69)		(70)	(48)	(49)	(69)
No abnormality detected	67	69	49	49	44		67	47	49	37	67		67	47	49	67
Periarthritis, fibrosing				1												1
Mineralization	3	12	9	6	5		3	1	2	2	2		3	1	2	2

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	01 mg/kg /day	01 50 mg/kg /day	50 mg/kg /day	50 200 mg/kg /day	200 mg/kg /day	300 mg/kg /day	01 mg/kg /day	01 50 mg/kg /day	50 mg/kg /day	50 200 mg/kg /day	200 mg/kg /day	300 mg/kg /day
DIGESTIVE SYSTEM - TONGUE:												
Squamous cell hyperplasia				(1)				(1)				
Cyst, NOS												
SALIVARY GLAND - MANDIBULAR:												
No abnormality detected	(70)	(63)	(56)	(70)			(70)	(66)	(60)	(42)	(70)	
Mineralization, arteriolar	6	5	5	7			6	4	6	4	7	
SALIVARY GLAND - PAROTID:												
No abnormality detected	(64)	(58)	(60)	(56)	(69)		(69)	(63)	(47)	(60)	(68)	
Hyperplasia, ductular, focal	6	5	5	6			6	4	4	3	6	
Sialadenitis, ductular, neutrophilic												
Thromboses, multifocal												
Atrophy	2	1	1	1								
Vacuolation, acinar cell												
Mineralization, ductal												
Mineralization, arteriolar												

Figures in parentheses represent the number of animals from which this tissue was examined.  
The absence of a numeral indicates that the lesion specified was not identified.

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Table 4 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS																						
	GROUP						SEXES																
	0.1 mg/kg /day		0.5 mg/kg /day		50 mg/kg /day		200 mg/kg /day		MALES		FEMALES												
	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	01	
DIGESTIVE SYSTEM:-																							
SALIVARY GLAND - PAROTID:																							
Granuloma, mineralized, focal																							
Ectasia, ductular																							
SALIVARY GLAND - SUBLINGUAL:																							
No abnormality detected																							
Mineralization, arteriolar																							
LIVER:																							
No abnormality detected																							
Eosinophilic cell focus																							
Basophilic cell focus																							
Clear cell focus																							
Vacuolated cell focus																							
Mixed cell focus																							
Necrosis, hepatocellular																							
Hyperplasia, hepatocellular, regenerative																							

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

(1,000/00) (Study Completed)

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings\*

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0.5 mg/kg /day		5 mg/kg /day		200 mg/kg /day		0.5 mg/kg /day		5 mg/kg /day		200 mg/kg /day	
DIGESTIVE SYSTEM-												
LIVER,												
Spongiosis hepatic	10	11	10	17	14							
Hypertrophy, hepatocellular, centrilobular												
mild	1	5	5	14	24	2	4	4	12	23	31	3
moderate			1	6	15					3	7	
Cholangitis												
Biliary hyperplasia	14	10	14	10	12	8	4	4	7	3	6	
Cyst, biliary	1			1						2	4	
Cyst, NOS				1								
Hematopoiesis, extramedullary						5		2		3	2	
Lipidosis, focal	1	1	1			2			1	1		
Vacuolation, hepatocellular	27	30	30	38	18	36	39	39	31	35	29	
Thrombus	1	1	1									
Inflammation, serosal, mixed										1		
Infarct					3			1		1	1	

\*Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS												
	GROUP	MALES						FEMALES					
		0	0.5	5	50	200		0	0.5	5	50	200	
	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day		
DIGESTIVE SYSTEM:-													
LIVER:	(70)	(70)	(70)	(70)	(70)		(70)	(70)	(70)	(70)	(70)		
Hemorrhage, subcapsular							1						
Fibrosis, focal	1							1					
Congestion	2	4				1						1	
Arteritis	1												
Angiectasis							1						
Ectasia, bile duct													
Pigmentation		1											
PANCREAS:	(69)	(61)	(43)	(58)	(70)		(70)	(50)	(51)	(42)	(70)		
No abnormality detected	23	22	25	17	24		51	34	43	26	44		
Islet cell hyperplasia	17	5	13	14	9		8	3	2	6	4		
Acinar cell hyperplasia	2	3	1	3	8					1	2		
Focus of acinar cell alteration, basophilic	3												
Pancreatitis	3	5	2	1	1		2	3	2	3	4		
Atrophy, lobular	22	22	20	22	28		7	5	4	7	12		

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

CS9074 (Study Completed)

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day		01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	
<b>DIGESTIVE SYSTEM:-</b>												
<b>PANCREAS:</b>												
Atrophy, diffuse			1		1							
Myointimal proliferation with medial degeneration, arteriolar				1	2							1
Polyarteritis nodosa	3	3	5	5	5							3
Thrombus	1			1	1							
Metaplasia, hepatocyte, focal												
Hemorrhage, acute, focal												
Mineralization, arteriolar	3	7	5	3								
<b>ESOPHAGUS:</b>												
No abnormality detected	(70)	(61)	(61)	(57)	(69)							(70)
Inflammation, chronic, serosa	70	61	60	57	69							49
Ectasia			1									
<b>STOMACH:</b>												
No abnormality detected	(70)	(70)	(70)	(70)	(70)							(70)
	23	21										14

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

CS9034 ( Study Completed )



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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	(70)	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	(70)
DIGESTIVE SYSTEM:-												
STOMACH:												
Hyperplasia, squamous cell, nonglandular	10	9	9	2	5	(70)						
Hyperplasia, basal cell, nonglandular	1		1	3	7	(70)						
Hyperkeratosis, nonglandular	7	3	6	3	1	(70)						
Ulceration, nonglandular	7	3	1	1		(70)						
Ectopic squamous mucosa, fundus, focal	1		1		2	(70)						
Polyarthritis nodosa	1		2	2	2	(70)						
Arteritis, mixed, focal			1			(70)						
Vacuolation, parietal cell					1	(70)						
Mineralization	3	10	12	4	1	(70)						
Inflammation, esophageal, mixed						(70)						
Infarction, fundus, focal						(70)						
Hemorrhage, acute, fundus	1					(70)						
Erosion, nonglandular, focal						(70)						

Figures in parentheses represent the number of animals from which this tissue was examined.  
The absence of a numeral indicates that the lesion specified was not identified.

CG9024 ( Study Completed )

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS												
	GROUP	MALES						FEMALES					
		01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	01 mg/kg /day	0.51 mg/kg /day	51 mg/kg /day	501 mg/kg /day	2001 mg/kg /day	01 mg/kg /day	0.51 mg/kg /day
DIGESTIVE SYSTEM:-													
STOMACH:													
Dilation, glandular, fundus	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)
Cyst, fundus	26	30	37	12	10	31	40	24	32	26	1		
Cyst, keratinized, nonglandular		1	2	1		1	1			1			
INTESTINE:													
No abnormality detected	(70)	(61)	(42)	(58)	(69)	(70)	(52)	(49)	(42)	(70)			
Enteritis, neutrophilic	61	52	53	47	44	64	41	40	33	59			
Polyarteritis nodosa			1	1	1								
Mineralization, uremic						1							
Mineralization, arterial							1						
Ectasia		1											
Congestion, acute	(66)	(61)	(62)	(58)	(70)	(65)	(48)	(49)	(42)	(69)			
JEJUNUM:													
No abnormality detected	48	38	44	36	44	59	33	34	28	59			
Enteritis, mixed				1									

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

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Table 6 (Cont'd)  
Summary of Non-neoplastic Microscopic Findings

FINDINGS	ROUHERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0	0.5	5	50	200	2000	0	0.5	5	50	200	2000
DIGESTIVE SYSTEM-												
JEJUNUM	(68)	(63)	(62)	(58)	(70)		(69)	(68)	(49)	(42)	(69)	
Infection, focal									1			
Polyarteritis nodosa				1	1							
Mineralization, arteriolar												
Intussusception			1									
Ectasia												
ILEUM	(70)	(61)	(62)	(58)	(70)		(70)	(68)	(48)	(42)	(70)	
No abnormality detected	52	42	41	41	49		64	36	36	32	63	
Enteritis, mixed												
Infection, focal										1		
Polyarteritis nodosa												
Mineralization, arteriolar												
Intussusception			1									

Figures in parentheses represent the number of animals from which this tissue was examined. The absence of a numeral indicates that the lesion specified was not identified.

CG9024 ( Study Completed )

11/1/91

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