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16-DEC-92  
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PLACES V8.206

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	
DIGESTIVE SYSTEM:- COLON:	(69)	(41)	(52)	(57)	(70)		(70)	(40)	(48)	(42)	(70)	
No abnormality detected	33	41	50	47	51		63	43	36	37	60	
Inferction				1	1		1		1			
Polyarteritis nodosa				1	1							
Mineralization, submucosa, uremia		2					1					
Mineralization, arteriolar	1							1				
Ectasia									1			
CECUM:									(1)			
No abnormality detected				1					1			
Dilatation												
RECTUM:	(1)											
Dilatation												
MESENTERY:	(2)	(3)	(2)	(2)	(3)		(1)	(1)	(3)		(2)	
Polyarteritis nodosa			1	2	2							2
Arteritis, 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	GROUP	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
		MALES						FEMALES					
		0.1 mg/kg /day	0.5 mg/kg /day	1 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day	0.1 mg/kg /day	0.5 mg/kg /day	1 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day
<b>DIGESTIVE SYSTEM:-</b>													
<b>MESENTERY:</b>		(3)	(3)	(2)	(2)	(3)		(1)	(3)			(2)	
Thrombosis		1						1					
Inflammation/granuloma		1							1				
<b>UROGENITAL SYSTEM:-</b>													
<b>KIDNEY:</b>		(70)	(70)	(70)	(70)	(70)		(70)	(70)	(70)	(70)	(70)	
No abnormality detected		6	2	1	2			13	11	7	9	3	
Nephropathy													
minimal		25	27	22	10	7		32	34	43	38	37	
mild		17	13	14	17	14		9	13	6	10	22	
moderate		11	12	13	18	16		1	3	5	5	12	
severe		10	14	19	22	33		1	1	3	5	6	
Pyelonephritis		3	2			1						1	
Pyelitis		4	2	5	4	2		7	3	4	3		
Hydronephrosis		3	2		1	4			1	2			
Thrombus, venous		2	2	2	3	4					1	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.

CE9024 ( Study Completed )

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

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0.1 mg/kg /day	0.5 mg/kg /day	1 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day	0.1 mg/kg /day	0.5 mg/kg /day	1 mg/kg /day	5 mg/kg /day	50 mg/kg /day	200 mg/kg /day
UROGENITAL SYSTEMS:-												
KIDNEY,												
Hyperplasia, tubular cell, focal				1								
Degeneration, hyalin droplet				2								
Degeneration, tubular												
Hemostasis, extramedullary												
Mineralization	2	2	1	1			23	37	15	6	0	0
Mineralization, arterial				1								
Calculus, pelvic, bilateral												
Hyperplasia, urothelial	4	4	3	5	2		1	1	3	1	4	
Cyst	1	2	2	2	2		2	2	1		2	
Hemorrhage, subcapsular, acute, unilateral												
Congestion, acute, bilateral									1			
Pigmentation, cuticular							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								
GROUP	01	0.51	51	501	2001	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	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day	mg/kg /day
UROGENITAL SYSTEMS:-															
URINARY BLADDER:															
No abnormality detected	(70)	(61)	(62)	(58)	(70)	(70)	(44)	(48)	(40)	(67)					
Cystitis	56	50	53	48	60	63	63	43	40	64					
Hyperplasia, epithelial	7	10	7	6	2	3	1	2							
Urolithiasis	6	5	5	4	4	4	1	3							
Mineralization, tunical, uranic		1													
Inflammation, aerosol, mixed		1													
Hemorrhage, acute		2					1								
Ectasia	8	3	3	2	3										1
Blood in lumen															
URAEThRA:	(1)														
Urethritis, neutrophilic	1														
TESTIS/EPIDIDYMIS:															
No abnormality detected	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)					
Hyperplasia, interstitial cell	35	35	35	30	21										

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 INCIDENCES OF MICROSCOPIC OBSERVATIONS											
	MALES						FEMALES					
	0)	0.5)	1)	5)	50)	200)	0)	0.5)	1)	5)	50)	200)
	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
	/day	/day	/day	/day	/day	/day	/day	/day	/day	/day	/day	/day
	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)
UROGENITAL SYSTEMS:-												
TESTIS/EPIDIDYDITIS,												
Polyarteritis nodosa, testicular												
mild	16	13	20	26	22							
moderate	6	5	3	3	11							
severe				2	6							
Polyarteritis nodosa, epididymal, unilateral	1		1	1								
Degeneration, tubular, testicular												
mild	11	7	14	12	14							
moderate	5	7	7	7	15							
severe	2	4			4							
Mineralization, arteriolar, testicular	3	4										
Spermatocoele, epididymal	1	3		1								
Inflammatory cell infiltrate, mixed, epididymal, unilateral, focal												
Infarction	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									
	GROUP	01	0.51	51	501	2001	01	0.51	51	501	2001	01	0.51	51	501	2001
UROGENITAL SYSTEMS:																
PROSTATE:																
No abnormality detected	(69)	(40)	(62)	(56)	(59)											
Prostatitis	22	15	24	25	31											
Hyperplasia, epithelial, reactive	47	45	34	33	37											
Neutocytosis, focal	19	19	10	12	10											
1																
SCMINAL VESICLES:																
No abnormality detected	(69)	(59)	(61)	(56)	(69)											
Vesiculitis	45	56	57	54	68											
1	3	4	3	3	3											
Hyperplasia, epithelial, reactive																
OVARY:																
No abnormality detected	(70)	(70)	(68)	(69)	(70)	(70)	(70)	(68)	(69)	(70)						
Hyperplasia, Sertoliform	33	33	23	20	26											
minimal	12	14	21	21	16											
mild	8	6	10	12	12											
moderate	1	1	5	5	5											

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

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

FINDINGS	MIXED INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	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	
URGENTINAL SYSTEMS:-												
OVARY:												
Cyst, NOS												
UTERUS:												
No abnormality detected												
Metritis, granulomatous, necrotizing												
Endometritis, neutrophilic												
Hyperplasia, endometrial												
Cyst, endometrial												
Menorrhage, endometrial, acute, focal												
Dilation												
VAGINA:												
Vaginitis, neutrophilic												
ENDOCRINE SYSTEM:-												
PITUITARY:												
No abnormality detected												

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	31	50	700		0	0.51	31	50	700	
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:												
Hyperplasia, para distalis	(70)	(65)	(67)	(66)	(70)	(70)	(62)	(64)	(63)	(70)		
Hyperplasia, focal, para intermedia	10	4	10	13	12		0	7	5	9		
Proliferation, Rathke's pouch elements												
Inflammatory cell infiltrate, mixed												
Cyst, NOS, para distalis	3	1	4	2	4	2			1	4		
Cyst, craniopharyngeal	1	1		1	2	1			1			
Cyst, NOS, para intermedia	5	2	4	10	0	2	6	1	1	2		
Cyst, NOS, para nervosa, multiple					1							
Pigmented macrophages	1	1	1		1				1	1		
Angiectasis, focal												
Cholesterol clefts	10	9	4	11	15	2				1		
ADRENAL:												
No abnormality detected	(70)	(61)	(62)	(57)	(70)	(70)	(55)	(52)	(44)	(70)		
Cortical hyperplasia	16	0	9	17	18	4	4	4	6	3		
	64	41	41	32	34	45	27	29	25	47		

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	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
ENDOCRINE SYSTEM:-	(70)	(81)	(62)	(57)	(70)	(70)	(55)	(52)	(44)	(70)	(70)	
ADRENAL:												
Medullary hyperplasia	2	7	6	5	12	3	3		1	1	1	
Degeneration/vacuolation, cortical		5	2	2	2	5	4	3	2	3	3	
Angiectasis, cortical	5	5	2	1	4	48	38	38	30	57	57	
Thrombosis		1		1	1		1	3	1			
Metaplasia, osseous, subcapsular, unilateral, focal						1						
Accessory adrenocortical tissue	14	10	15	5	19	5	1	1	5	11	11	
Hematomatosis, extramedullary		1	2	1		12	3	2	6	5	5	
Inferct	1		1		3				1			
Necrosis, cortical, unilateral, focal					1							
Hemorrhage, acute		1	1		2							
Fibrosis, cortical, unilateral												
Cyst, mineralized, cortical, unilateral, focal												
Congestion, cortical	2	3	2	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					
	01	0.51	51	501	2001		01	0.51	51	501	2001		01	0.51	51	501	2001	
	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg		mg/kg	mg/kg	mg/kg	mg/kg	mg/kg		mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	
	/day	/day	/day	/day	/day		/day	/day	/day	/day	/day		/day	/day	/day	/day	/day	
ENDOCRINE SYSTEM:-																		
ADRENAL:																		
Atrophy, cortical, bilateral	(70)	(81)	(62)	(57)	(70)								(70)	(55)	(52)	(44)	(70)	
THYROID:																		
No abnormality detected	(70)	(70)	(69)	(69)	(70)								(70)	(70)	(70)	(70)	(70)	
Follicular cell hyperplasia, focal	33	39	42	36	15								46	48	44	52	25	
Hypertrophy, follicular cell	1			2	2								2				4	
Mild																		
Cyst, follicular	1	1	6	6	20										2	15		
C-cell hyperplasia																		
Cyst, ultimobranchial	6	5	7	2	6								9	7	13	8	5	
Mineralization, arteriolar	4	2	3	4	13								4	3	3	1	8	
Inflammatory cell infiltrate, plasmacytic, multifocal	1		1	1														
PARATHYROID:																		
No abnormality detected	(68)	(56)	(60)	(55)	(59)								(61)	(44)	(40)	(41)	(68)	
Macrosis, unilateral	60	43	44	39	46								59	43	45	36	63	

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.

089027 ( Study Completed )

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PLACES V8.204

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

FINDINGS	NUMERIC INCIDENCE OF MICROSCOPIC OBSERVATIONS											
	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	
ENDOCRINE SYSTEM:-												
PARATHYROID:												
Hyperplasia	7	14	16	14	23		2	1	3	4	5	
Hyperplasia, focal				1								
Fibrosis, capsular, bilateral				1								
NERVOUS SYSTEM:-												
BRAIN:												
No abnormality detected	49	35	40	41	47		31	22	23	19	40	
Gliosis, reactive	1											
Hypertrophy, granular cell, meninges, focal			1									
Mineralization	1				2							
Hemorrhage	1	1	1	3	1		1	3	2	1	2	
Dilation, ventricular	1	5	1	1	1		2	1	1	3	2	
Cyst, cortical	1											
Angiectasis, unilateral, focal							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	
SPECIAL SENSE ORGANS:-											
HARDERIAN GLAND:											
Pigmentation				(1)							
1											
EYEBALL GLAND:											
SQUAMOUS CELL CARCINOMA (H), metastasizing				(1)	(3)			(2)	(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.

Q99024 ( Study Completed )

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**APPENDIX 3A**

Fischer 344 Rat Carcinogenicity Study  
Histopathology - Tumor Data.

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APPEARS THIS WAY  
ON ORIGINAL

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220/94 Rat, Carcinogenicity study p.o.

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 21
DAYS : ALL		SEX: MALE					
GROUP:		-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:		50	50	50	50	50	
abdominal cavity	# Ex	3	0	2	0	0	
mesothelioma		1	0	0	0	0	
carcinoma, not other specified		0	0	1	0	0	
adipose tissue	# Ex	9	0	0	3	1	
adrenal 1	# Ex	48	50	49	50	50	
cortical cell adenoma		0	1	2	2	0	
medullary tumor, mixed type		0	0	0	0	1	
medullary tumor		8	5	9	7	3	
adrenal 2	# Ex	49	49	48	50	50	
cortical cell adenoma		0	0	0	2	0	
medullary tumor		15	2	5	2	5	
all organs	# Ex	8	13	17	14	16	
aorta	# Ex	50	50	49	50	50	
body openings	# Ex	0	0	0	0	0	
bone	# Ex	0	1	0	0	1	
brain	# Ex	50	49	50	50	47	
meningioma		0	0	0	0	1	
cecum	# Ex	49	49	48	50	47	
colon	# Ex	49	49	48	50	48	
adenocarcinoma		0	0	1	0	0	

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220/94 Rat, Carcinogenicity study p.o.

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 22
DAYS : ALL	SEX: MALE					
GROUP:	-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:	50	50	50	50	50	
diaphragma	# Ex 0	# 0	# 0	# 0	# 0	
duodenum	# Ex 49	# 49	# 48	# 50	# 48	
ear/auditory duct	# Ex 0	# 0	# 0	# 0	# 0	
epididymis 1	# Ex 48	# 48	# 49	# 49	# 48	
epididymis 2	# Ex 46	# 48	# 49	# 50	# 46	
esophagus	# Ex 50	# 49	# 50	# 50	# 49	
extremities	# Ex 0	# 0	# 0	# 0	# 0	
eye 1	# Ex 50	# 48	# 49	# 49	# 48	
eye 2	# Ex 50	# 48	# 49	# 49	# 48	
forestomach	# Ex 50	# 50	# 50	# 50	# 50	
general used preferred terms	# Ex 0	# 0	# 0	# 1	# 0	
glandular stomach (Grimelius)	# Ex 39	# 32	# 32	# 34	# 30	
glandular stomach (antrum)	# Ex 49	# 49	# 50	# 50	# 50	
glandular stomach (fundus)	# Ex 50	# 49	# 50	# 50	# 50	
neuroendocrine tumor	0	0	0	4	7	



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**Project Summary Table**

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 23
DAYS : ALL		SEX: MALE					
GROUP:		0 mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:		50	50	50	50	50	
haematopoetic system	# Ex 27	16	21	20	27		
leukemia, granulocytic	0	0	0	1	2		
sarcoma, histiocytic	1	0	0	0	0		
LGL leukemia	19	13	16	7	13		
lymphoma/leukemia, unclassif.	7	3	5	12	8		
harderian gland 1	# Ex 49	50	50	50	49		
harderian gland 2	# Ex 50	50	50	50	49		
heart	# Ex 50	50	50	50	50		
endocard. proliferative lesion	0	0	1	0	0		
ileum	# Ex 49	49	48	50	47		
ischialic nerve	# Ex 50	50	48	50	48		
jejunum	# Ex 49	49	48	50	48		
leiomyoma	0	0	1	0	0		
joints	# Ex 0	0	0	0	0		
kidney 1	# Ex 50	50	50	50	50		
kidney 2	# Ex 50	50	50	50	49		
liver	# Ex 50	50	50	50	50		
hepatocellular adenoma	5	4	1	0	4		
hepatocellular carcinoma	0	1	0	0	0		

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**Project Summary Table**

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 24
DAYS : ALL		SEX: MALE					
GROUP:		-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:		50	50	50	50	50	
		#	#	#	#	#	
lum.spinal cord, bone m.	# Ex	47	46	48	50	50	
lung	# Ex	50	50	49	50	50	
bronch.-alv. adenoma		0	0	0	1	1	
lung ass.lym.no.(non-protocol)	# Ex	25	13	18	15	22	
lymph node mesent.	# Ex	48	48	46	47	48	
lymph node submand.	# Ex	49	49	49	50	48	
lymph nodes (non-protocol)	# Ex	5	7	7	0	2	
mammary gland	# Ex	47	48	49	48	49	
liposarcoma, myxoid type		0	0	0	1	0	
fibrous histiocytoma		0	0	1	0	0	
fibroma		0	0	0	0	2	
fibroadenoma		1	0	1	0	0	
nasal/paranasal cavities	# Ex	49	48	46	49	50	
squamous cell papilloma		0	0	0	0	1	
oral cavity (and teeth)	# Ex	50	50	50	50	49	
squamous cell carcinoma		2	1	0	3	1	
other tissues	# Ex	0	0	0	0	0	
pancreas	# Ex	48	48	49	48	48	
islet cell adenoma		1	1	1	1	1	

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Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 25
DAYS : ALL	SEX: MALE					
GROUP:	-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:	50	50	50	50	50	
parathyroid 1 adenoma	# Ex 41 2	# 40 0	# 39 0	# 36 1	# 40 0	
parathyroid 2 adenoma	# Ex 36 0	# 35 0	# 32 1	# 28 1	# 38 2	
penis	# Ex 0	# 0	# 0	# 0	# 0	
pituitary	# Ex 46	# 43	# 46	# 45	# 44	
pars distalis adenoma	9	11	5	9	10	
pars intermedia adenoma	0	0	1	0	0	
pars distalis adenocarcinoma	0	0	0	1	2	
preputial gland	# Ex 1	# 1	# 0	# 2	# 1	
adenoma	0	1	0	0	0	
adenocarcinoma	0	0	0	1	0	
prostate	# Ex 50	# 49	# 45	# 49	# 50	
adenoma	0	0	0	0	1	
rectum	# Ex 49	# 49	# 48	# 50	# 48	
salivary gland, parot.	# Ex 48	# 47	# 49	# 50	# 48	
salivary gland, submand.	# Ex 48	# 49	# 50	# 50	# 49	
seminal vesicle	# Ex 50	# 50	# 45	# 49	# 50	
skeletal muscle quadriceps	# Ex 50	# 50	# 50	# 50	# 50	

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Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143  
DAYS : ALL

FATES: ALL  
SEX: MALE

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GROUP: -- mg/kg    0 mg/kg    5 mg/kg    15 mg/kg    50 mg/kg  
NUMBER OF ANIMALS:    50            50            50            50            50

	# Ex	#	#	#	#	#
skin	# Ex	49	50	50	48	50
schwannoma		2	0	0	0	0
basal cell carcinoma		0	0	0	0	1
squamous cell papilloma		1	0	1	0	0
fibrous histiocytoma		2	1	1	1	1
sebaceous adenocarcinoma		1	0	0	0	0
keratoscantomata		0	2	1	1	0
squamous cell carcinoma		1	1	0	1	0
fibroma		1	0	0	0	0
lipoma		0	0	0	1	0
spleen	# Ex	50	49	50	50	49
tail	# Ex	1	0	0	0	0
testis 1	# Ex	50	49	50	50	50
Leydig cell tumor		44	37	39	43	44
adenocarcinoma, rete testis		0	0	0	0	1
testis 2	# Ex	50	49	50	49	50
Leydig cell tumor		43	32	36	44	43
thorac.spinal cord, bone m.	# Ex	49	50	49	50	50
thoracic cavity	# Ex	1	0	1	1	2
thymus	# Ex	49	44	44	43	40
thyroid 1	# Ex	48	48	48	48	45
follicle cell adenoma		0	0	0	1	0
follicle cell carcinoma		0	0	1	0	0
C-cell tumor		6	9	7	7	6

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**Project Summary Table**

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143  
DAYS : ALL

FATES: ALL  
SEX: MALE

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GROUP:		-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg
NUMBER OF ANIMALS:		50	50	50	50	50
		#	#	#	#	#
thyroid 2	# Ex	46	47	47	46	44
follicular cell adenoma		1	0	0	0	0
C-cell tumor		3	3	2	7	3
tibia	# Ex	49	49	50	50	50
tongue	# Ex	49	50	50	50	50
trachea	# Ex	49	50	50	49	49
ureter	# Ex	0	0	0	0	0
urinary bladder	# Ex	50	50	47	50	49
papilloma, transitional cell		1	0	0	0	1

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Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 28
DAYS : ALL	SEX: FEMALE					
GROUP:	-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:	50	50	50	50	50	
abdominal cavity	# Ex 0	# 0	# 0	# 2	# 1	
adipose tissue	# Ex 1	# 1	# 1	# 3	# 0	
adrenal 1	# Ex 46	# 50	# 49	# 50	# 50	
cortical cell adenoma	3	0	0	0	1	
medullary tumor	1	1	1	1	1	
adrenal 2	# Ex 46	# 50	# 49	# 50	# 50	
cortical cell adenoma	1	0	0	0	0	
cortical cell carcinoma	0	1	0	0	0	
medullary tumor, mixed-type	1	0	0	0	0	
medullary tumor	0	1	0	0	1	
all organs	# Ex 14	# 25	# 30	# 23	# 28	
aorta	# Ex 50	# 50	# 50	# 50	# 49	
body openings	# Ex 0	# 0	# 0	# 0	# 0	
bone	# Ex 0	# 1	# 0	# 0	# 0	
brain	# Ex 48	# 49	# 50	# 50	# 50	
cecum	# Ex 48	# 49	# 50	# 50	# 50	
clitoral gland	# Ex 1	# 1	# 1	# 2	# 0	
papilloma, squamous cell	0	0	1	1	0	
adenocarcinoma	1	0	0	1	0	

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**Project Summary Table**

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 29
DAYS : ALL		SEX: FEMALE					
GROUP:		-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:		50	50	50	50	50	
colon	# Ex 48	# 50	# 50	# 50	# 50	# 50	
diaphragm	# Ex 0	# 0	# 0	# 0	# 0	# 0	
duodenum	# Ex 49	# 50	# 50	# 50	# 50	# 50	
ear/auditory duct	# Ex 0	# 0	# 0	# 0	# 0	# 0	
esophagus	# Ex 50	# 50	# 50	# 50	# 50	# 49	
extremities	# Ex 0	# 0	# 0	# 0	# 0	# 0	
eye 1	# Ex 45	# 47	# 48	# 47	# 47	# 47	
eye 2	# Ex 45	# 47	# 49	# 47	# 46	# 46	
leiomyoma	0	1	0	0	0	0	
forestomach	# Ex 49	# 50	# 50	# 50	# 50	# 50	
general used preferred terms	# Ex 0	# 0	# 0	# 0	# 0	# 0	
glandular stomach (Grimelius)	# Ex 35	# 23	# 17	# 25	# 20	# 20	
glandular stomach (antrum)	# Ex 49	# 50	# 46	# 49	# 47	# 47	
glandular stomach (fundus)	# Ex 49	# 50	# 50	# 50	# 50	# 50	
neuroendocrine tumor	0	0	4	12	7	7	

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Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 30
DAYS : ALL		SEX: FEMALE					
GROUP:		-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:		50	50	50	50	50	
haematopoetic system	# Ex	8	7	3	8	7	
LGL leukemia		7	3	2	5	1	
lymphoma/leukemia, unclassif.		1	4	1	3	6	
harderian gland. 1	# Ex	50	50	50	50	50	
harderian gland. 2	# Ex	50	50	50	50	50	
heart	# Ex	49	50	50	50	50	
ileum	# Ex	48	49	50	49	50	
ischialic nerve	# Ex	50	50	48	48	47	
jejunum	# Ex	48	50	50	49	50	
joints	# Ex	0	0	0	0	0	
kidney 1	# Ex	47	50	49	50	50	
kidney 2	# Ex	47	50	49	50	50	
liver	# Ex	50	50	50	50	50	
hepatocellular adenoma		3	1	0	2	3	
hepatocellular carcinoma		0	0	0	1	0	
lumbar spinal cord, bone m.	# Ex	48	49	48	48	48	

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Project Summary Table

SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 31
DAYS: ALL	SEX: FEMALE					
GROUP:	-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:	50	50	50	50	50	
Lung	# Ex 50	# 50	# 50	# 50	# 50	
lung ass. lym. no. (non-protocol)	# Ex 13	# 11	# 9	# 18	# 19	
lymph node mesent.	# Ex 47	# 50	# 48	# 49	# 50	
lymph node submand.	# Ex 48	# 46	# 48	# 47	# 44	
lymph nodes (non-protocol)	# Ex 2	# 2	# 1	# 1	# 1	
mammary gland	# Ex 50	# 48	# 46	# 49	# 47	
adenoma	0	0	0	1	1	
fibroadenoma	1	1	1	1	0	
adenocarcinoma	2	0	0	0	0	
nasal/paranasal cavities	# Ex 49	# 49	# 49	# 49	# 49	
oral cavity (and teeth)	# Ex 50	# 48	# 48	# 49	# 49	
squamous cell carcinoma	4	1	2	2	2	
other tissues	# Ex 0	# 0	# 0	# 0	# 0	
ovaries	# Ex 47	# 50	# 50	# 50	# 50	
pancreas	# Ex 47	# 48	# 50	# 49	# 49	
islet cell adenocarcinoma	0	0	0	1	0	
parathyroid 1	# Ex 43	# 42	# 39	# 42	# 43	
adenoma	0	0	0	1	1	

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SUMMARY: Incidence of NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 32
DAYS : ALL	SEX: FEMALE					
GROUP:	-- mg/kg	0 mg/kg	5 mg/kg	15 mg/kg	50 mg/kg	
NUMBER OF ANIMALS:	50	50	50	50	50	
parathyroid 2	# Ex 33	# 30	# 28	# 29	# 29	
pituitary	# Ex 44	# 43	# 43	# 46	# 41	
pars distalis adenoma	19	7	9	6	11	
pars distalis adenocarcinoma	1	0	0	1	1	
rectum	# Ex 48	# 50	# 50	# 50	# 50	
salivary gland, parot.	# Ex 48	# 50	# 49	# 48	# 50	
salivary gland, submand.	# Ex 48	# 50	# 50	# 50	# 50	
skeletal muscle quadriceps	# Ex 50	# 50	# 50	# 50	# 50	
skin	# Ex 50	# 50	# 48	# 48	# 49	
fibrous histiocytoma	0	0	1	0	0	
hair follicle tumor	0	0	0	0	1	
keratoacanthoma	0	0	0	0	1	
squamous cell carcinoma	0	0	1	3	1	
spleen	# Ex 49	# 50	# 50	# 50	# 50	
tail	# Ex 0	# 0	# 0	# 0	# 0	
thorac. spinal cord, bone m.	# Ex 49	# 50	# 50	# 50	# 49	
thoracic cavity	# Ex 0	# 0	# 0	# 0	# 2	
thyroid	# Ex 45	# 48	# 45	# 46	# 49	

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