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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 33
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	
thyroid 1	# Ex 46	50	49	49	49	
follicle cell carcinoma	0	1	0	0	0	
C-cell tumor	8	1	1	2	3	
thyroid 2	# Ex 46	49	46	48	48	
C-cell tumor	1	4	2	3	2	
tibia	# Ex 50	50	50	50	49	
tongue	# Ex 49	50	50	50	50	
trachea	# Ex 49	50	50	50	50	
ureter	# Ex 0	0	0	0	0	
urinary bladder	# Ex 50	50	45	45	48	
uterus / ut.-cervix / vagina	# Ex 49	50	50	50	50	
polyp	9	2	4	6	3	
granular cell tumor	0	0	1	0	0	

(End of Report)

APPEARS THIS WAY
ON ORIGINAL

APPENDIX 3B

Fischer 344 Rat Carcinogenicity Study
Histopathology - Non-neoplastic Lesion Data

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**APPEARS THIS WAY
ON ORIGINAL**

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SUMMARY: Incidence of NON-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

	#	#	#	#	#
abdominal cavity	# Ex 3	0	2	0	0
peritonitis	0	0	1	0	0
adipose tissue	# Ex 9	0	0	3	1
necrosis	3	0	0	2	0
purulent inflammation	1	0	0	0	0
chronic steatitis	4	0	0	2	1
edema	1	0	0	0	0
adrenal 1	# Ex 48	50	49	50	50
cortical fat vacuoles	29	14	17	19	20
cortical hyperplasia	12	10	13	17	13
cortical necrosis	0	2	2	1	0
hemorrhage	2	3	0	0	1
blood-filled cyst	2	10	6	8	6
extramedullary hematopoiesis	1	2	0	0	0
calcification	2	0	0	0	0
pigment deposits	17	16	17	25	35
extracapsular hernia	1	0	0	0	0
cortical hypertrophy	1	0	0	0	0
z.glomerulosa hypertrophy	3	0	0	0	0
z.fasciculata hypertrophy	1	0	0	0	0
extracortical nodule	6	5	2	4	6
lympho-histiocytic infiltr.	1	0	0	0	0
cortical atrophy / necrosis	0	0	0	0	1
hyperemia / congestion	1	5	6	7	14
thrombosis	3	0	0	0	1
purulent adrenalitis	1	0	0	0	1
medullary hyperplasia	32	14	21	31	26
intravascular foreign material	0	0	0	0	1
eosinophilic infiltr.	1	0	0	0	0
leukocytostasis	0	6	2	5	5
adrenal 2	# Ex 49	49	48	50	50
cortical fat vacuoles	26	19	16	18	19
cortical hyperplasia	11	13	10	13	10
cortical necrosis	1	1	1	0	0
hemorrhage	1	3	0	0	1

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PROJECT ID. NO: KR0143		FATES: ALL					PAGE 35
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	
		#	#	#	#	#	
adrenal 2	# Ex	49	49	48	50	50	
blood-filled cyst		3	12	4	2	6	
extramedullary hematopoiesis		1	1	0	0	0	
calcification		1	0	0	0	0	
pigment deposits		13	17	14	28	34	
extracapsular hernia		1	0	1	0	0	
cortical hypertrophy		2	0	0	0	0	
extracortical nodule		7	8	4	7	3	
lympho-histiocytic infiltr.		0	0	0	1	0	
cortical atrophy / necrosis		0	0	0	0	1	
hyperemia / congestion		1	4	3	7	11	
thrombosis		0	0	1	0	1	
purulent adrenalitis		1	0	0	0	1	
medullary hyperplasia		28	11	18	23	27	
intravascular foreign material		0	0	0	0	1	
eosinophilic infiltr.		1	0	0	0	0	
leukocytostasis		0	3	3	5	5	
all organs	# Ex	8	13	17	14	16	
bacterial growth		1	0	2	0	0	
autolysis		8	13	16	14	16	
aorta	# Ex	50	50	49	50	50	
medial calcification		3	1	0	0	0	
peri- / vasculitis		0	1	0	0	0	
leukocytostasis		0	0	0	0	2	
body openings	# Ex	0	0	0	0	0	
bone	# Ex	0	1	0	0	1	
chronic osteomyelitis		0	0	0	0	1	
healed fracture		0	1	0	0	0	
brain	# Ex	50	49	50	50	47	
lympho-histiocytic infiltr.		0	2	0	1	1	
hemorrhage		0	0	0	1	5	

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SUMMARY: Incidence of NON-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	#	#	#	#	#
brain	# Ex	50	49	50	50	47
thalamic compression		2	2	0	1	3
internal hydrocephalus		0	0	0	0	1
red malacia		1	0	4	1	2
white malacia		0	1	0	1	1
satellitosis		0	1	0	0	2
neuronal / axonal degeneration		1	12	2	4	1
hyperemia / congestion		2	0	2	1	6
meningeal calcification		1	0	0	0	1
bacterial growth		0	1	0	0	0
neuronal calcification		0	0	0	1	0
septic meningoencephalitis		1	0	0	0	0
intravascular foreign material		0	0	0	0	1
cecum	# Ex	49	49	48	50	47
enteritis		1	0	0	2	0
edema		1	0	0	2	0
peri- / vasculitis		0	0	1	0	0
necrosis		1	0	1	1	0
lymphocytic hyperplasia		0	0	0	1	2
intramucosal hemorrhage		0	0	0	1	0
bacterial growth		0	0	0	1	0
dilatation		0	0	0	1	0
colon	# Ex	49	49	48	50	48
ulcer		1	1	0	0	0
edema		0	0	0	0	1
hemctodes		0	1	1	0	0
necrosis		1	0	1	0	0
lymphocytic hyperplasia		0	0	0	0	1
hemorrhage		0	0	1	0	0
enteritis		1	0	0	0	0
mucosal atrophy		0	0	0	1	0
sub- / mucosal edema		0	1	0	0	0
diaphragm	# Ex	0	0	0	0	0

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SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

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PROJECT ID. NO: KR0143
DAYS : ALL

FATES: 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

	#	#	#	#	#
duodenum	# Ex 49	49	48	50	48
ectopic intramucosal pancreas	0	0	1	1	0
ear/auditory duct	# Ex 0	0	0	0	0
epididymis 1	# Ex 48	48	49	49	48
atrophy	42	37	36	41	38
aspermia	2	0	0	1	1
inflammation	1	0	0	0	0
lympho-histiocytic infiltr.	1	0	0	0	0
dyspermia	2	4	4	1	3
oligospermia	1	5	2	3	1
fibrosis	11	13	12	8	9
epididymis 2	# Ex 46	48	49	50	46
degeneration	0	0	0	1	0
atrophy	39	36	37	42	36
aspermia	2	0	0	0	1
oligospermia	1	6	0	4	0
dyspermia	4	5	4	0	2
fibrosis	9	13	13	8	9
peri- / vasculitis	0	0	1	0	0
tubular calcification	0	0	0	0	1
esophagus	# Ex 50	49	50	50	49
peri- / epi- / esophagitis	1	0	0	0	0
sub- / mucosal bleeding	0	1	0	0	0
extremities	# Ex 0	0	0	0	0
eye 1	# Ex 50	48	49	49	48
keratitis	1	0	0	1	2
iritis	1	0	0	0	0
uveitis	2	0	1	2	0
retinal degener. / atrophy	12	12	12	8	7

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DAYS : ALL

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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

	#	#	#	#	#
eye 1	# Ex 50	48	49	49	48
orbital inflammation	1	0	0	0	1
anterior chamber hemorrhage	2	0	0	1	1
optical nerve degeneration	0	0	0	0	1
granuloma	13	5	6	4	8
connective tissue calcific.	39	35	33	36	36
periorbital blood	2	2	0	1	3
lympho-histiocytic infiltr.	1	2	0	3	0
hemosiderin deposits	1	0	0	0	0
degeneration of vitreous body	1	0	0	3	1
bacterial growth	0	1	0	0	0
leukocytostasis	0	0	0	0	1
intravascular foreign material	0	0	0	0	1
eye 2	# Ex 50	48	49	49	48
keratitis	0	0	0	1	1
uveitis	0	0	0	1	1
retinal degener. / atrophy	12	12	13	9	9
anterior chamber hemorrhage	0	0	0	1	1
granuloma	8	7	5	5	8
connective tissue calcific.	39	36	32	34	38
periorbital blood	16	6	1	11	2
lympho-histiocytic infiltr.	1	1	0	0	0
degeneration of vitreous body	1	1	0	3	0
leukocytostasis	1	0	0	1	1
intravascular foreign material	0	0	0	0	1
forestomach	# Ex 50	50	50	50	50
hyperkeratosis	0	1	0	0	0
erosion	2	0	0	0	0
ulcer	1	0	0	0	0
sub. edema	1	0	0	1	0
calcification, muscular	0	0	4	7	2
hyperplasia	2	1	2	4	8
general used preferred terms	# Ex 0	0	0	1	0
angiomatous hyperplasia	0	0	0	1	0

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FATES: ALL

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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

	#	#	#	#	#
glandular stomach (Grimellus) # Ex	39	32	32	34	30
GPC, diffuse	39	31	31	32	30
GPC, focal hyperplasia	0	0	4	3	2
GPC, chains	2	0	14	15	12
GPC, micronodules	0	0	0	2	3
GPC, submucosal growth	0	0	0	4	6
GPC, decreased	0	1	1	1	0
GPC, distribution	39	32	32	32	30
glandular stomach (antrum) # Ex	49	49	50	50	50
mucosal hyperplasia	0	9	6	12	19
erosion	4	8	6	0	1
ulcer	0	0	1	0	0
epithelial hyperplasia	0	0	3	5	4
vascular necrosis in adnexes	1	0	0	0	0
fat necrosis	1	0	0	0	0
glandular ectasia	0	1	0	0	0
epithelial cyst	0	0	1	0	0
squamous cell metaplasia	0	0	0	1	0
subm. mixed cell infiltr.	0	3	0	1	0
lymphfollicle	0	0	4	4	10
glandular stomach (fundus) # Ex	50	49	50	50	50
parietal cell vacuolation	0	0	0	0	6
mucosal hyperplasia/folding	15	13	47	49	44
gland. ectasia	17	16	36	42	41
cyst	0	0	1	6	6
erosion	20	19	8	9	3
ulcer	4	2	0	2	0
necrosis	0	0	0	0	4
eosinophilic chief cells	0	0	34	40	39
subm. mixed cell infiltration	1	1	4	2	2
subm. edema	3	2	5	5	1
subm. glandular hyperplasia	0	0	1	2	0
bleeding	1	0	0	0	0
foveolar hyperplasia	2	2	0	0	0
basal fibrosis	11	7	20	26	25
vascular calcification	4	8	6	7	1
cell atrophy	5	0	0	0	0

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PROJECT ID. NO: KR0143	FATES: ALL					PAGE 40
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	
glandular stomach (fundus)	# Ex 50	49	50	50	50	
congestion/hyperemia	0	9	0	1	1	
calcification, muscular	0	1	0	1	0	
mucosal lymphfollicles	0	0	0	1	11	
regenerative hyperplasia	0	0	0	2	11	
vasculitis	0	0	0	0	2	
eosinophilic infiltr.	0	0	4	20	23	
haematopoetic system	# Ex 27	16	21	20	27	
reactive hyperplasia	0	0	0	0	4	
harderian gland 1	# Ex 49	50	50	50	49	
chronic inflammation	0	5	2	3	3	
lobular atrophy	0	0	1	0	0	
chromodacryorrhea	48	48	50	49	48	
intraglandular blood	0	4	4	2	4	
lobular hypertrophy	1	0	0	0	0	
lympho-histiocytic infiltr.	9	13	9	11	9	
acute inflammation	1	0	0	2	0	
necrosis	1	0	0	0	0	
granuloma	0	0	0	0	1	
acinar hyperplasia	0	0	0	1	0	
hyperemia / congestion	0	0	0	2	0	
bacterial growth	0	1	0	0	0	
leukocytostasis	0	0	0	0	1	
harderian gland 2	# Ex 50	50	50	50	49	
chronic inflammation	1	4	1	5	5	
lobular atrophy	1	0	0	1	0	
chromodacryorrhea	49	48	48	49	49	
intraglandular blood	11	19	9	19	4	
lympho-histiocytic infiltr.	10	2	8	8	9	
granuloma	1	0	0	0	2	
acinar hyperplasia	1	1	0	0	0	
hyperemia / congestion	0	0	0	1	0	
bacterial growth	0	1	0	0	0	
leukocytostasis	0	0	0	0	1	

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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	50	50	50	50
heart		50	50	50	50
chronic myocarditis	24	20	16	23	19
myocardial hemosiderosis	5	2	4	1	7
myocardial fibrosis	32	17	23	18	28
peri- / vasculitis	2	2	2	1	1
fiber calcification	0	1	0	1	0
chondroid metaplasia	0	3	1	4	3
myocardial degeneration	1	0	3	6	2
lympho-histiocytic infiltr.	7	6	6	5	7
vascular calcification	33	30	31	33	28
leukocytostasis	0	0	1	0	1
thrombosis	5	0	1	3	7
septic myo-/endocarditis	2	1	1	1	1
hyperemia / congestion	0	0	0	0	1
granuloma	0	0	1	0	0
fibrinoid media necrosis	0	1	0	0	0
intravascular foreign material	0	0	0	0	1
ileum	# Ex 49	49	48	50	47
lymphocytic hyperplasia	2	9	7	6	6
necrosis	0	0	1	0	0
hyperemia / congestion	0	0	1	0	0
mucosal hyperplasia	0	1	0	0	0
ischialic nerve	# Ex 50	50	48	50	48
peri- / neuritis	0	0	1	0	0
leukocytostasis	0	0	0	0	1
jejunum	# Ex 49	49	48	50	48
ulcer	0	0	1	0	0
necrosis	1	0	0	0	0
lymphocytic hyperplasia	0	1	0	1	1
reparative granulation tissue	0	0	1	0	0
joints	# Ex 0	0	0	0	0

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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

	#	#	#	#	#
kidney 1	# Ex 50	50	50	50	50
chron. progressive nephropathy	43	41	36	42	40
dilated tubules, casts	2	0	3	1	4
pyelonephritis	1	1	0	0	0
pelvic epith. calcification	0	0	2	1	0
interstitial nephritis	0	1	2	3	4
pigment deposits	30	30	30	28	34
tubular calcification	0	5	5	5	2
tubular cell regeneration	0	1	2	2	3
hyperemia / congestion	1	5	9	7	7
lympho-histiocytic infiltr.	0	1	1	2	1
leukocytostasis	0	0	0	1	2
agonal bleeding	0	1	1	0	0
intravascular foreign material	0	0	0	0	1
necrosis	2	0	0	0	0
septic nephritis	1	0	0	1	0
tubular cell hyperplasia	0	0	0	0	1
kidney 2	# Ex 50	50	50	50	49
chron. progressive nephropathy	43	41	36	42	40
dilated tubules, casts	2	0	3	1	4
pyelonephritis	0	1	0	0	0
interstitial nephritis	0	1	2	3	4
pigment deposits	30	29	30	27	34
tubular calcification	1	4	5	3	0
tubular cell regeneration	0	0	0	1	2
hyperemia / congestion	1	5	9	7	7
lympho-histiocytic infiltr.	0	1	0	3	0
leukocytostasis	0	0	0	1	2
agonal bleeding	0	1	0	0	0
intravascular foreign material	0	0	0	0	1
necrosis	1	0	0	0	0
septic nephritis	1	0	0	0	0
Liver	# Ex 50	50	50	50	50
hepatitis	2	0	0	2	1
bile duct proliferation	49	48	46	50	49
clear cell focus	10	12	7	15	13
eosinophilic cell focus	9	12	1	5	8

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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

	#	#	#	#	#
liver	# Ex	50	50	50	50
basophilic cell focus		20	14	13	17
necrosis		15	11	16	15
hemorrhage		13	8	11	8
periductal fibrosis/inflamat.		43	43	38	44
pigment deposits		2	4	8	7
peliosis		22	12	13	19
extramedullary hematopoiesis		1	0	0	0
hepatocellular vacuolation		1	0	0	0
hepatocell. fatty vacuolation		16	17	20	19
leukocytostasis		2	9	7	2
lympho-histiocytic infiltr.		2	10	9	1
hyperemia / congestion		7	13	20	21
apoptosis		3	2	4	0
spongiosis		10	9	9	9
regenerat. hepat. hyperplasia		22	17	16	14
capsular fibrosis		0	0	0	0
centrilobular hypertrophy		1	13	12	19
Mallory bodies, intracytoplas.		1	0	0	0
eosinophilic infiltr.		0	1	1	0
intravascular foreign material		0	0	0	0
granuloma		2	3	2	5
thrombosis		1	0	0	4
hepatocellular hypertrophy		1	0	0	0
deformed, herniated lobe		0	2	0	1
lumb.spinal cord, bone m.	# Ex	47	46	48	50
axon degeneration		27	15	4	9
ganglial cell degeneration		0	1	0	0
ectopic epidermoid cyst		0	1	0	0
granulomatous inflammation		0	0	1	0
red malacia		0	0	0	1
hemorrhage		0	0	0	1
intravascular foreign material		0	0	0	0
peri- / vasculitis		0	0	1	0
high cellularity		3	0	1	0
reactive hyperplasia		2	3	1	3

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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

	#	#	#	#	#
Lung	# Ex	50	50	50	50
hyperemia / congestion	17	28	29	32	33
lympho-histiocytic infiltr.	5	9	4	5	9
alveolar histiocytosis	17	10	19	15	13
purulent bronchopneumonia	0	6	3	2	1
foreign-body granuloma	2	7	6	2	2
intraalveolar blood	6	11	8	2	10
alveolar edema	2	1	1	1	0
pleuritis	0	1	0	0	0
interstitial fibrosis	2	0	0	0	0
vascular calcification	7	1	3	4	0
cholesterol clefts	1	1	0	0	0
emphysema	8	9	9	13	10
eosinophilic infiltr.	0	0	0	0	1
granuloma	0	0	0	2	1
pigment in macrophages	10	5	8	9	6
thrombosis	1	0	1	1	0
bronch.-alv. hyperplasia	1	1	2	1	2
leukocytostasis	3	0	3	2	5
aspirated plant material	0	5	2	1	0
intravascular foreign material	0	0	0	0	1
granulomatous pneumonia	0	2	0	0	0
perivascular bleeding(s)	1	1	0	0	0
Lung ass.lym.no.(non-protocol)# Ex	25	13	18	15	22
erythrophagocytosis	9	2	7	5	3
pigment deposits	3	1	1	0	1
sinus histiocytosis	1	1	0	0	0
hemosiderosis	10	3	4	7	7
sinus plasmocytosis	0	0	0	0	1
hyperemia / congestion	0	0	1	2	1
blood resorption	0	0	0	1	0
lymphoid depletion	0	0	0	0	1
granulocytic infiltr.	0	1	0	0	0
sinusoidal edema	0	1	0	0	0
Lymph node mesent.	# Ex	48	46	47	48
sinus histiocytosis	3	2	3	7	11
erythrophagocytosis	1	1	2	1	1

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143
DAYS : ALLFATES: ALL
SEX: MALE

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

	# Ex	#	#	#	#	#
Lymph node mesent.		48	48	46	47	48
hemosiderosis	1	0	0	1	0	0
hyperemia / congestion	0	0	0	2	0	0
mastocytosis	1	2	2	2	1	2
cyst	0	0	0	1	0	0
plasmacytosis	1	0	0	0	0	0
follicular hyperplasia	0	0	0	1	0	1
histiocytic nodule / granuloma	16	27	19	36	33	33
parafollicular hyperplasia	0	0	0	0	0	2
peri- / vasculitis	0	0	0	1	0	0
lymphoid depletion	0	0	0	1	2	1
sinusoidal edema / dilatation	0	0	0	2	0	1
reactive hyperplasia	1	0	0	0	2	2
intravascular foreign material	0	0	0	0	0	1
necrosis	0	1	0	0	0	0
lymphadenitis	1	1	0	0	0	0
bacterial growth	0	1	0	0	0	0
Lymph node submand.	# Ex	49	49	49	50	48
erythrophagocytosis	5	2	2	3	2	2
hyperemia / congestion	1	3	3	6	2	6
cystic	0	0	0	1	0	0
hemosiderosis	1	5	5	1	1	0
plasmacytosis	17	21	10	22	22	22
follicular hyperplasia	1	6	6	6	5	7
parafollicular hyperplasia	1	2	2	3	2	5
sinus histiocytosis	2	0	0	0	1	1
hemorrhage	0	0	0	0	0	2
granuloma	1	0	0	0	1	0
black pigment deposits	5	3	3	5	3	2
necrosis	1	0	0	1	0	0
bacterial growth	0	1	0	0	0	0
sinusoidal edema	0	0	0	0	0	1
lymphoid depletion	1	0	0	0	1	0
reactive hyperplasia	1	1	1	1	1	3
histiocytic nodule / granuloma	0	0	0	0	2	0
intravascular foreign material	0	0	0	0	0	1

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143	FATES: ALL					PAGE 46
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	
lymph nodes (non-protocol)	# Ex 5	# 7	# 7	# 0	# 2	
erythrophagocytosis	1	0	1	0	0	
follicular hyperplasia	0	0	1	0	0	
hemosiderin deposits	0	0	0	0	1	
hyperemia / congestion	0	0	1	0	0	
sinusoidal edema / dilatation	0	1	1	0	0	
histiocytic nodule / granuloma	0	0	0	0	1	
 mammary gland	# Ex 47	# 48	# 49	# 48	# 49	
inflammation	0	0	0	0	1	
galactocele	2	1	2	7	0	
hematoma	1	0	1	0	1	
pigment deposits	7	0	6	4	17	
dilated ducts	4	0	0	1	3	
lympho-histiocytic infiltr.	1	0	0	0	0	
fat necrosis	2	0	0	0	0	
hyperemia / congestion	0	0	0	0	1	
leukocytostasis	0	0	0	0	1	
hyperplasia of lipocytes	0	0	1	0	0	
epithelial hyperplasia	0	0	0	2	4	
 nasal/paranasal cavities	# Ex 49	# 48	# 46	# 49	# 50	
purulent inflammation	5	4	5	6	11	
inhaled foreign material	4	3	5	5	8	
non-purulent inflammation	1	0	0	0	0	
mucus accumulation	1	0	0	0	1	
hyperemia / congestion	2	1	4	3	16	
mucosal calcification	0	0	0	1	0	
goblet-cell hyperplasia	3	13	2	19	7	
squamous metaplasia	0	0	0	0	1	
respir. epithel degen.	1	1	1	2	2	
thrombosis	8	5	6	4	6	
hemorrhage	0	1	0	0	0	
leukocytostasis	0	0	0	0	1	
lympho-histiocytic infiltr.	0	0	0	0	2	
squamous cell hyperplasia	0	0	1	1	2	
osteoclastic osteomyelitis	1	0	1	0	0	

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Project Summary Table

SUMMARY: Incidence of NON-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

	#	#	#	#	#
oral cavity (and teeth)	# Ex 50	50	50	50	49
orolaryngeal & oesoph. impact.	10	10	17	10	11
orolaryngeal granulomas	26	22	19	25	28
purulent laryngitis	13	9	15	16	11
lympho-histiocytic infiltr.	30	24	23	25	23
mucosal erosion	0	0	3	1	0
mucosal ulceration	2	0	0	0	1
cystic secretory duct dilat.	19	14	19	14	15
laryngeal cartilage degenerat.	18	16	18	18	19
laryngeal submucosal edema	0	1	1	2	6
ranula	0	0	1	0	0
goblet cell hyper-/metaplasia	0	0	0	0	1
squamous cell metaplasia	0	0	0	1	0
other tissues	# Ex 0	0	0	0	0
pancreas	# Ex 48	48	49	48	48
lympho-histiocytic infiltr.	5	2	0	6	4
increased apoptosis	0	1	0	0	0
acinar cell atrophy	1	0	0	0	0
acinar cell hyperplasia	0	0	0	0	1
islet hemosiderosis	1	0	0	0	1
pigment deposits	0	1	0	0	0
islet cell hyperplasia	7	4	0	3	0
hyperemia / congestion	1	0	2	0	0
basophilic focus	0	1	0	1	0
peri- / vasculitis	0	0	1	0	0
edema	2	0	4	0	2
chronic atrophic pancreatitis	17	14	16	20	22
ductal cell regeneration	7	14	15	19	18
necrosis	0	1	0	1	0
intravascular foreign material	0	0	0	0	1
ductal cyst	1	0	0	0	0
leukocytostasis	0	0	0	0	1
acinar cell hypertrophy	0	0	1	0	0
bacterial growth	0	0	0	0	1

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Project Summary Table

SUMMARY: Incidence of NON-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

	#	#	#	#	#
parathyroid 1	# Ex 41	40	39	36	40
hyperplasia	5	3	1	0	4
hypertrophy	1	2	0	0	1
lympho-histiocytic infiltr.	1	0	0	0	0
hyperemia / congestion	0	0	0	1	0
parathyroid 2	# Ex 36	35	32	28	38
hyperplasia	1	0	3	0	5
fibrosis	1	0	0	0	0
hypertrophy	0	0	0	0	1
lympho-histiocytic infiltr.	1	0	0	0	0
hyperemia / congestion	0	0	0	1	0
penis	# Ex 0	0	0	0	0
pituitary	# Ex 46	43	46	45	44
hemoglobin /cholesterol clefts	0	0	1	0	1
cavern / cyst	4	3	1	1	6
hemosiderosis	1	1	0	3	7
hemorrhage	2	3	1	0	4
pars distalis hyperplasia	7	6	4	7	12
pars intermedia hyperplasia	0	0	0	0	2
hyperemia / congestion	0	0	1	0	3
leukocytostasis	1	0	0	0	1
reactive hemopoe. hyperplasia	0	0	0	0	1
intravascular foreign material	0	0	0	0	1
preputial gland	# Ex 1	1	0	2	1
inflammation	0	0	0	1	1
cyst	1	0	0	1	1
prostate	# Ex 50	49	45	49	50
hyperplasia	7	8	3	9	4
atrophy	41	41	33	46	45
degeneration	1	0	0	0	0
inflammation	10	7	9	10	8

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 49
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	
prostate	# Ex 50	49	45	49	50		
edema	1	0	0	1	1		
fibrosis	0	0	2	0	0		
leukocytostasis	0	0	0	0	1		
rectum	# Ex 49	49	48	50	48		
nematodes	1	0	1	0	0		
lymphocytic hyperplasia	0	0	0	3	1		
fat necrosis	1	0	0	0	0		
mucosal atrophy	0	0	0	1	0		
salivary gland, parot.	# Ex 48	47	49	50	48		
interstitial fibrosis	0	1	0	1	1		
acinar necrosis	1	0	0	0	0		
lobular atrophy	1	1	1	1	1		
edema	1	1	0	0	0		
periglandular inflammation	1	1	0	0	0		
lympho-histiocytic infiltr.	1	0	0	0	0		
basophilic focus	1	1	2	1	0		
intravascular foreign material	0	0	0	0	1		
salivary gland, submand.	# Ex 48	49	50	50	49		
lobular atrophy	0	1	0	0	0		
periglandular inflammation	1	0	0	0	0		
lympho-histiocytic infiltr.	0	0	1	0	2		
mucous acinar hyperplasia	0	0	0	1	0		
serous acinar hyperplasia	1	1	3	2	2		
basophilic focus	0	0	3	0	0		
seminal vesicle	# Ex 50	50	45	49	50		
hyperplasia	2	0	0	0	2		
atrophy	41	40	34	44	41		
inflammation	5	0	1	0	0		
fibrosis	9	7	5	7	10		
leukocytostasis	0	0	0	0	1		

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 50
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	
	#	#	#	#	#	#	
skeletal muscle quadriceps	# Ex	50	50	50	50	50	
myodegeneration		3	0	0	0	0	
lympho-histiocytic infiltr.		0	1	0	0	0	
bacterial growth		0	1	0	0	0	
leukocytostasis		0	0	0	1	0	
intravascular foreign material		0	0	0	0	1	
skin	# Ex	49	50	50	48	50	
dermatitis		5	2	0	2	1	
dermal fibrosis/calcif.		3	0	1	0	0	
ulcer		1	0	0	2	0	
abscess		0	1	1	1	1	
epithelial cell hyperplasia		0	1	1	1	0	
hemorrhage		1	0	0	0	0	
hyperemia / congestion		1	0	0	0	0	
orthokerat. hyperkeratosis		1	0	0	0	0	
lympho-histiocytic infiltr.		1	0	0	0	0	
ostitis / osteomyelitis		0	0	0	1	0	
epidermal cyst		1	0	0	1	0	
spleen	# Ex	50	49	50	50	49	
extramedullary hematopoiesis		16	18	13	24	23	
hemsiderosis		10	20	20	21	17	
chronic perisplenitis		4	8	4	1	4	
fibrosis		3	6	7	8	5	
hemorrhagic necrosis		4	2	3	0	0	
hemorrhage		0	3	1	1	1	
lymphoid atrophy		0	2	1	1	0	
follicular hyperplasia		0	1	4	0	5	
parafollicular hyperplasia		1	5	3	2	2	
hyperemia / congestion		24	20	23	27	36	
reticulum cell hyperplasia		0	1	2	1	2	
splenitis		0	1	0	0	0	
reactive hyperplasia		2	4	3	6	3	
serosal cyst		0	1	0	0	0	
lymphoid depletion		1	1	0	2	1	
intravascular foreign material		0	0	0	0	1	

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143 FATES: ALL PAGE 51
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

	#	#	#	#	#
tail	# Ex 1	0	0	0	0
necrosis	1	0	0	0	0
testis 1	# Ex 50	49	50	50	50
tubular degeneration	1	1	0	0	0
tubular atrophy	46	43	42	46	43
Leydig cell hyperplasia	11	20	19	14	9
lympho-histiocytic infiltr.	0	1	1	0	0
spermatocele	0	0	0	1	0
oligospermia	1	0	0	1	0
tubular calcification	25	16	25	30	30
aspermia	0	0	0	0	1
hemorrhages	1	0	3	3	6
hyperemia / congestion	1	0	0	5	0
Leydig cell pigmentation	1	1	0	0	0
granulomatous inflammation	0	1	1	5	4
necrosis	0	0	1	0	0
testis 2	# Ex 50	49	50	49	50
tubular degeneration	0	0	1	1	0
tubular atrophy	46	43	42	42	42
Leydig cell hyperplasia	10	17	10	12	9
lympho-histiocytic infiltr.	0	0	0	1	0
oligospermia	1	0	0	1	0
tubular calcification	19	17	24	28	28
aspermia	0	0	0	0	1
hemorrhages	1	0	1	2	7
hyperemia / congestion	1	0	0	3	0
Leydig cell pigmentation	1	1	0	1	0
granulomatous inflammation	0	3	2	5	3
necrosis	0	1	0	0	0
thorac.spinal cord, bone m.	# Ex 49	50	49	50	50
axon degeneration	2	1	1	1	2
red malacia	0	0	0	1	1
hemorrhage	0	0	0	1	1
osteomyelofibrosis	1	0	0	0	0
peri- / vasculitis	0	0	1	0	0

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 52
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	
thorac.spinal cord, bone m.	# Ex	49	50	49	50	50	
intravascular foreign material		0	0	0	0	1	
high cellularity		3	0	1	0	3	
reactive hyperplasia		2	3	1	3	6	
thoracic cavity	# Ex	1	0	1	1	2	
pleuritis		0	0	0	1	1	
thymus	# Ex	49	44	44	43	40	
involution		41	38	31	40	38	
epithelial hyperplasia		2	2	2	4	3	
hyperemia / congestion		3	5	11	6	3	
peri- / vasculitis		0	0	1	0	0	
agonal bleeding		1	2	5	1	0	
edema		1	0	0	0	0	
brown fat tissue		2	0	0	0	0	
bacterial growth		0	1	0	0	0	
reactive hyperplasia		0	0	0	0	1	
pleuritis		1	0	0	0	0	
necrosis		1	0	0	0	0	
thyroid 1	# Ex	48	48	48	48	45	
follicular cell activation		2	18	14	11	9	
hyperemia / congestion		0	2	4	4	6	
large follicles		2	0	0	0	1	
C-cell hyperplasia, diffuse		0	7	15	18	2	
follicular cell hyperplasia		1	3	0	1	6	
branchiogenic cyst		2	2	1	3	2	
cystic follicle		0	0	0	1	1	
lympho-histiocytic infiltr.		1	0	0	0	0	
C-cell hyperplasia		12	14	5	10	11	
thyroid 2	# Ex	46	47	47	44	44	
follicular cell activation		2	19	15	11	9	
hyperemia / congestion		0	2	4	4	6	
large follicles		1	0	0	0	0	
C-cell hyperplasia, diffuse		0	8	16	16	2	

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143
DAYS : ALL

FATES: ALL
SEX: MALE

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

		#	#	#	#	#
thyroid 2	# Ex	46	47	47	44	44
follicular cell hyperplasia		1	1	1	1	2
branchiogenic cyst		1	0	0	0	0
cystic follicle		0	0	0	0	1
intracellular colloid storage		0	0	0	0	1
C-cell hyperplasia		4	9	4	12	3
tibia	# Ex	49	49	50	50	50
hemorrhage		0	3	1	2	0
necrosis		0	0	1	0	0
osteomyelofibrosis		2	0	0	0	4
granulomatous inflammation		0	1	0	0	1
parvus formation / callus		0	0	0	0	1
bone marrow atrophy		0	0	1	0	0
high cellularity		5	0	1	0	2
subchondral cystoid defect		0	0	0	0	1
reactive hyperplasia		2	10	5	3	6
intravascular foreign material		0	0	0	0	1
tongue	# Ex	49	50	50	50	50
inflammation		1	0	1	0	0
peri- / vasculitis		2	1	1	1	1
myodegeneration		1	0	0	0	0
hyperkeratosis		0	0	0	0	1
vascular calcification		48	44	40	44	44
lympho-histiocytic infiltr.		0	0	1	0	0
intravascular foreign material		0	0	0	0	1
trachea	# Ex	49	50	50	49	49
intraluminal blood		0	0	1	0	0
ureter	# Ex	0	0	0	0	0
urinary bladder	# Ex	50	50	47	50	49
epithelial hyperplasia		2	0	0	0	0
acute cystitis		1	0	1	0	0

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143		FATES: ALL					PAGE 54
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	
urinary bladder	#	#	#	#	#	#	
	# Ex	50	50	47	50	49	
lympho-histiocytic infiltr.		0	1	1	0	2	
edema		2	5	1	5	4	
proteinaceous plug		0	3	2	3	0	
sub-, mucosal bleeding		0	0	0	0	1	
dilatation		0	5	1	2	7	
residuals of sediment		0	2	2	0	0	
leukocytostasis		0	0	1	0	2	

(End of Report)

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Project Summary Table

SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: KR0143 FATES: ALL PAGE 55
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
peritonitis	0	0	0	1	1
foreign material	0	0	0	0	1
adipose tissue	# Ex 1	1	1	3	0
necrosis	1	0	0	2	0
chronic steatitis	0	1	1	2	0
adrenal 1	# Ex 46	50	49	50	50
cortical fat vacuoles	10	6	4	6	9
cortical hyperplasia	22	10	6	7	5
cortical necrosis	0	0	2	0	1
hemorrhage	3	2	4	2	3
blood-filled cyst	9	4	4	2	9
pigment deposits	30	11	11	21	20
extracapsular hernia	0	0	0	0	1
extracortical nodule	5	2	4	3	4
lympho-histiocytic infiltr.	0	0	0	0	1
cortical atrophy / necrosis	0	1	0	0	0
hyperemia / congestion	5	9	8	16	16
agonal bleedings	0	1	1	0	0
purulent adrenalitis	0	0	0	0	1
medullary hyperplasia	11	5	3	3	7
leukocytostasis	1	0	1	5	2
adrenal 2	# Ex 46	50	49	50	50
cortical fat vacuoles	10	4	7	5	7
cortical hyperplasia	17	14	3	3	7
cortical necrosis	0	1	2	0	1
hemorrhage	1	3	3	1	4
blood-filled cyst	5	2	2	5	6
pigment deposits	31	13	10	20	17
extracapsular hernia	0	0	0	0	1
extracortical nodule	2	0	2	2	4
lympho-histiocytic infiltr.	0	0	0	0	1
cortical atrophy / necrosis	2	1	0	0	0
hyperemia / congestion	4	9	8	16	16
agonal bleedings	0	1	1	0	0

(Report Continued)