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Generation of Historical Control Data for the Hsd: Sprague Dawley® SD® rat for up to 104 Weeks

Study C11963

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Protocol Summary

I. PURPOSE

The purpose of this study was to generate historical control data for the Sprague Dawley® rat when administered daily by gavage for a period of 4, 13, 26, and 104 weeks. For each time period an untreated control group was kept under the same conditions which were not administered by gavage. The control group simulates the condition of animals in feeding studies, where the test substance is administered via the feed.

II. TEST SYSTEM	
Rationale:	Recognized by international guidelines as a recommended test system
Number of Animals:	Groups 1 to 6: 20 males and 20 females each Groups 7 and 8: 60 males and 60 females each
Age at delivery:	Approximately 6 weeks
Age at study start:	Approximately 11 weeks

III. TREATMENT	
Method:	Recognized by international guidelines as a recommended test system
Rationale:	Groups 1 to 6: 20 males and 20 females each Groups 7 and 8: 60 males and 60 females each
Frequency of Administration:	Daily, at approximately 24 hour intervals
Dose Volume:	10 mL/kg body weight (Groups 2, 4, 6, and 8)
Duration of Acclimatization Period:	At least 5 days
Duration of Treatment Period:	At least 28 days (Groups 1 and 2) At least 13 weeks (Groups 3 and 4) At least 26 weeks (Groups 5 and 6) At least 104 weeks (Groups 7 and 8)

IV. HUSBANDRY	
Conditions:	Target range of temperature: 22 ± 3oC, Relative humidity: 30-70%, Light cycle: 12 hours light/12 hours dark
Accommodations:	Makrolon type-4 with wire mesh tops, sterilized standard softwood bedding
Diet:	Standard Kliba Nafag 3433 rodent maintenance diet *ad libitum*
Water:	*Ad libitum* provided in water bottles

V. TEST ITEM	
Identification:	Water

VI. CLINICAL LABORATORY INVESTIGATIONS

Blood samples were drawn from the retro-orbital plexus from all animals under light isoflurane anesthesia. The animals were fasted in metabolism cages for approximately 18 hours before blood sampling but allowed access to water *ad libitum*. The samples were collected early in the working day to reduce biological variation caused by circadian rhythms.

Hematology

Tri-potassium-EDTA was used as anticoagulant during blood collection for Complete Blood Cell Count. Sodium citrate, 3.2% (1 part anticoagulant to 9 parts blood) was used as anticoagulant during blood collection for coagulation.

PARAMETER	UNIT	UNIT	INSTRUMENTATION
Erythrocyte count	T/L		ADVIA 120 hematology system (Bayer)
Hemoglobin	mmol/L		Advia 120
Hematocrit (relative)	rel.1		Advia 120
Mean corpuscular volume	fL		Advia 120
Red cell volume distribution width	rel.1		Advia 120
Mean corpuscular hemoglobin	fmol		Advia 120
Mean corpuscular hemoglobin concentration	mmol/L		Advia 120
Hemoglobin concentration distribution width	mmol/L		Advia 120
Reticulocyte count	relative rel.1	absolute G/L	Advia 120
Reticulocyte maturity index (low, medium, high fluorescence)	rel.1 rel.1 rel.1		Advia 120
Leukocyte count, total	G/L		Advia 120
Differential leukocyte count	relative	absolute	Advia 120

PARAMETER	UNIT	UNIT	INSTRUMENTATION
Neutrophils	rel.1	G/L	Advia 120
Eosinophils (relative and absolute	rel.1	G/L	Advia 120
Basophils	rel.1	G/L	Advia 120
Lymphocytes	rel.1	G/L	Advia 120
Monocytes	rel.1	G/L	Advia 120
Large unstained cells	rel.1	G/L	Advia 120
Platelet count	G/L		Advia 120

PARAMETER	METHOD	INSTRUMENTATION
Prothrombin time (=Thromboplastin time)	Clotting assay, thromboplastin from rabbit brain tissue, results as ratio of normal activity	STA-compact analyzer (Roche Diagnostics)
Activated partial thromboplastin time	Clotting assay, cephalin from rabbit cerebral tissue, silica surface activator	STA

Clinical Biochemistry

Lithium heparin was used as anticoagulant during blood collection.

PARAMETER	METHOD	INSTRUMENTATION
Glucose	Hexokinase/G6P-DH	Hitachi 917 (Roche)
Urea	Urease/GLDH	Hitachi 917
Creatinine	Enzymatic colorimetric test	Hitachi 917
Bilirubin, total	Reaction with 2,5-Dichloro-phenyl-diazonium salt	Hitachi 917
Cholesterol, total	Enzymatic, CHOD/PAP	Hitachi 917
Triglycerides	Glycerol-Kinase GPO/PAP method	Hitachi 917
Phospholipids	Phospholipase-Cholinoxidase-Peroxidase-reaction	Hitachi 917
Aspartate aminotransferase EC 2.6.1.1[1]	MDH/NADH coupled reaction	Hitachi 917
Alanine aminotransferase EC 2.6.1.2	LDH/NADH coupled reaction	Hitachi 917
Lactate dehydrogenase EC 1.1.1.27	NADH/LDH coupled reaction using pyruvate as substrate	Hitachi 917
Glutamate dehydrogenase EC 1.4.1.3	Standard method, optimized (DGKC)	Hitachi 917
Alkaline phosphatase EC 3.1.3.1	p-Nitrophenyl-phosphate as substrate	Hitachi 917
Gamma-glutamyl transferase EC 2.3.2.2	Substrate: L-gammaglutamyl- 3-carboxy- 4-nitroanilide	Hitachi 917
Creatine kinase EC 2.7.3.2	HK/ATP and G6P-DH/NADPH coupled reaction method	Hitachi 917

PARAMETER	METHOD	INSTRUMENTATION
Sodium	Ion selective electrode	Hitachi 917
Potassium	Ion selective electrode	Hitachi 917
Chloride	Ion selective electrode	Hitachi 917
Calcium	o-Cresolphthalein complexone method	Hitachi 917
Phosphorus	Phosphomolybdate reaction	Hitachi 917
Protein, total	Biuret reaction	Hitachi 917
Albumin	Bromocresol green method	Hitachi 917

GOOD LABORATORY PRACTICE

This study was performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice adopted May 18th, 2005 [RS 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th 1997 by decision of the OECD Council [C (97)186/Final].

ACCREDITATION

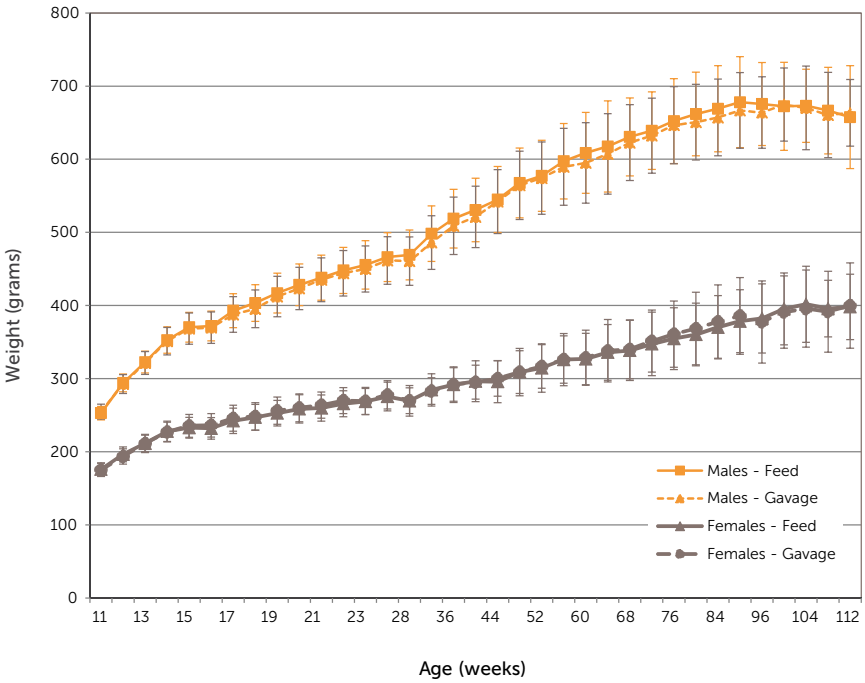
"RCC Ltd" is accredited as a test laboratory for the analysis in the fields of clinical chemistry, hematology, bloodcoagulation and urine diagnostics in accordance with the Standard ISO/IEC 17025 under accreditation number STS 085 by the Swiss Accreditation Service.

ANIMAL WELFARE

The study was performed in an AAALACi-accredited laboratory in accordance with the Swiss Animal Protection law.

[1] Identification of enzymes with EC-Number (Enzyme Commission) according to Enzyme Nomenclature, Recommendations (1972) of the IUPAC and IUB, Elsevier Scient. Publ. Comp., Amsterdam, 1973

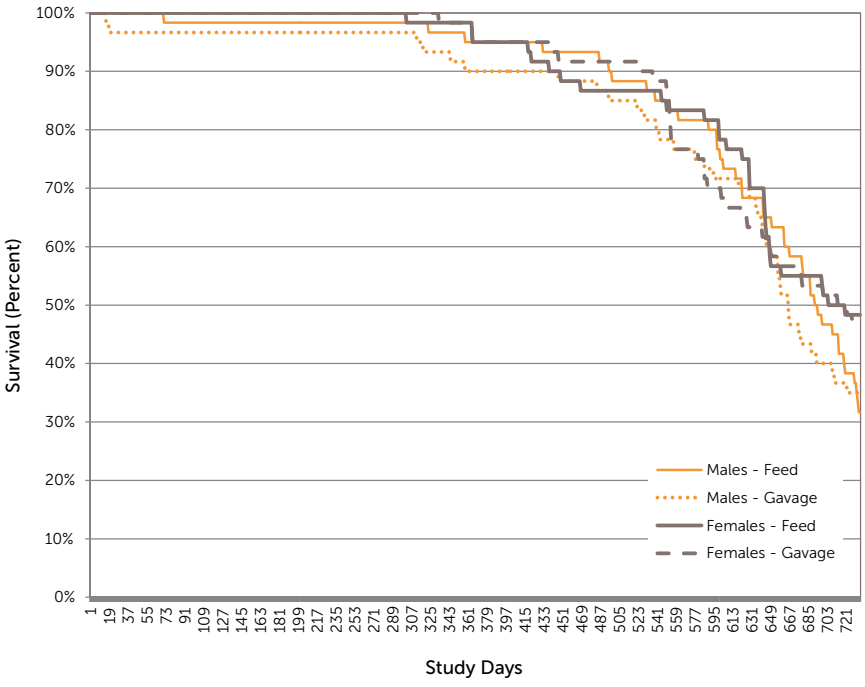
Hsd:Sprague Dawley® SD® 104 Week Growth Curve



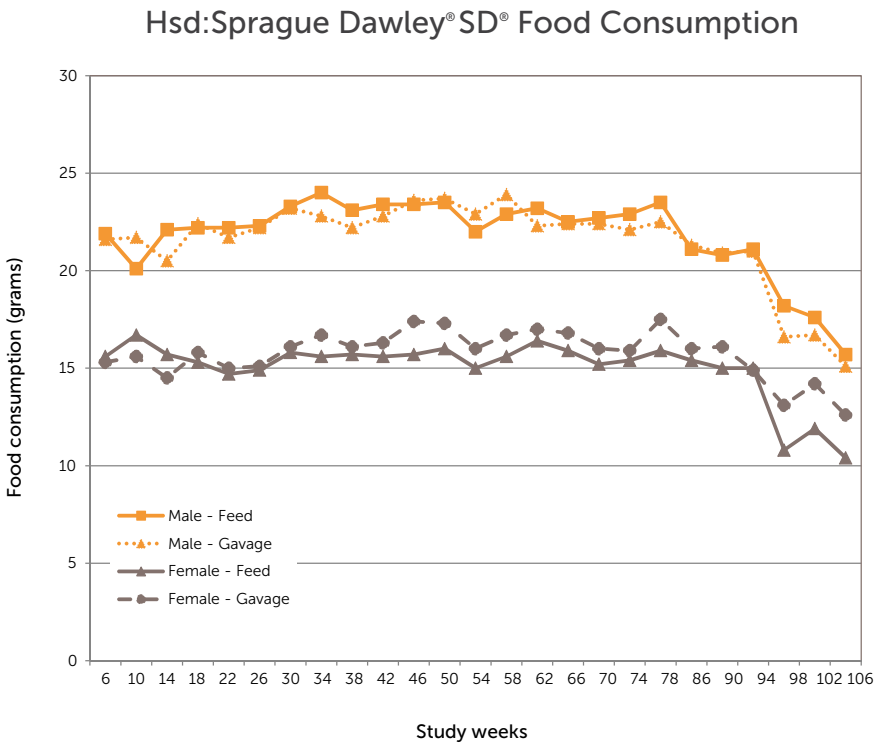
Age at study start: Approximately 11 weeks
Maintained on Kliba Nafag 3433
Study C11963

Growth data to be used as guideline only.
Data can be subject to differences in maintenance of rats.
Growth chart includes mean ± 2 SD's representative of population distribution.

Hsd:Sprague Dawley® SD® 104 Week Survival



Age at study start: Approximately 11 weeks
Maintained on Kliba Nafag 3433
Study C11963



Age at study start: Approximately 11 weeks
Maintained on Kliba Nafag 3433
Study C11963

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 1 MALES - FEED

COMPLETE BLOOD COUNT	UNITS	28 DAYS N = 20	13 WEEKS N = 20	26 WEEKS N = 20	104 WEEKS N = 19
Erythrocytes	T/l	9.05 ± 0.32	9.41 ± 0.32	9.61 ± 0.40	8.78 ± 0.56
Hemoglobin	mmol/l	10.6 ± 0.3	10.6 ± 0.2	10.8 ± 0.3	10.1 ± 0.5
Hematocrit	rel. 1	0.47 ± 0.01	0.47 ± 0.01	0.48 ± 0.02	0.46 ± 0.03
Mean Corpuscular Volume	fl	52 ± 1.4	49.6 ± 1.0	50.3 ± 0.8	53 ± 1.6
Red Cell Vol. Distr. Width	rel. 1	0.111 ± 0.003	0.123 ± 0.002	0.124 ± 0.003	0.134 ± 1.15
Mean Corpuscular Hemoglobin	fmol	1.17 ± 0.03	1.12 ± 0.03	1.12 ± 0.03	1.15 ± 0.04
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.43 ± 0.16	22.60 ± 0.22	22.35 ± 0.31	21.66 ± 0.27
Hemoglobin Conc. Distr. Width	mmol/l	1.68 ± 0.06	1.84 ± 0.06	1.86 ± 0.06	2.06 ± 0.11
Reticulocyte (Rel)*	rel. 1	0.021 ± 0.003	0.019 ± 0.002	0.021 ± 0.002	0.028 ± 0.01
Reticulocyte (Abs)	G/l	193 ± 27	174 ± 14	197 ± 22	247 ± 40
Maturity Index (L-Reti)*	rel. 1	0.561 ± 0.038	0.687 ± 0.029	0.592 ± 0.038	0.609 ± 0.067
Maturity Index (M-Reti)*	rel. 1	0.349 ± 0.016	0.268 ± 0.022	0.331 ± 0.025	0.331 ± 0.037
Maturity Index (H-Reti)*	rel. 1	0.088 ± 0.029	0.043 ± 0.014	0.074 ± 0.018	0.079 ± 0.03
Leukocytes, Total	G/l	12.36 ± 1.93	9.43 ± 1.27	10.72 ± 1.60	10.79 ± 2.93
Neutrophils *	rel. 1	0.142 ± 0.057	0.241 ± 0.068	0.234 ± 0.091	0.314 ± 0.073
Eosinophils *	rel. 1	0.011 ± 0.003	0.018 ± 0.004	0.020 ± 0.005	0.023 ± 0.01
Basophils *	rel. 1	0.007 ± 0.001	0.006 ± 0.002	0.007 ± 0.002	0.003 ± 0.00
Lymphocytes*	rel. 1	0.794 ± 0.057	0.695 ± 0.070	0.689 ± 0.092	0.603 ± 0.08
Monocytes*	rel. 1	0.029 ± 0.006	0.028 ± 0.007	0.038 ± 0.006	0.52 ± 0.01
Large Unstained Cells*	rel. 1	0.013 ± 0.005	0.007 ± 0.002	0.009 ± 0.002	0.005 ± 0.001
Neutrophils	G/l	1.91 ± 0.76	2.22 ± 0.79	2.63 ± 1.31	3.39 ± 1.77
Eosinophils	G/l	0.13 ± 0.04	0.16 ± 0.03	0.22 ± 0.06	0.24 ± 0.07
Basophils	G/l	0.08 ± 0.02	0.06 ± 0.02	0.08 ± 0.03	0.03 ± 0.01
Lymphocytes	G/l	9.71 ± 1.69	6.66 ± 0.93	7.29 ± 1.04	6.49 ± 1.40
Monocytes	G/l	0.37 ± 0.10	0.27 ± 0.08	0.41 ± 0.07	0.55 ± 0.22
Large Unstained Cells	G/l	0.16 ± 0.05	0.06 ± 0.02	0.10 ± 0.02	0.06 ± 0.02
Thrombocytes (Platelets)	G/l	888 ± 88	848 ± 104	894 ± 116	941 ± 188
Prothrombin Time*	rel. 1	0.87 ± 0.05	0.89 ± 0.07	0.84 ± 0.11	0.87 ± 0.08
Partial Thromboplastin Time *	sec	27.5 ± 1.7	26.1 ± 1.3	25.5 ± 2.4	20.9 ± 2.4

Data represents average ± one standard deviation
* Data represents median ± one standard deviation

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 2 MALES - GAVAGE

COMPLETE BLOOD COUNT	UNITS	28 DAYS n = 19	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 21
Erythrocytes	T/l	8.86 + 0.27	9.6 + 0.293	9.44 + 0.33	8.97 + 0.8
Hemoglobin	mmol/l	10.4 + 0.2	10.5 + 0.3	10.7 + 0.3	10.1 + 0.73
Hematocrit	rel. 1	0.46 + 0.01	0.47 + 0.01	0.47 + 0.02	0.47 + 0.03
Mean Corpuscular Volume	fl	51.8 + 1.2	49.7 + 1.4	50.3 + 0.8	53 + 1.9
Red Cell Vol. Distr. Width	rel. 1	0.112 + 0.003	0.124 + 0.003	0.123 + 0.003	0.136 + 0.01
Mean Corpuscular Hemoglobin	fmol	1.17 + 0.03	1.12 + 0.03	1.13 + 0.03	1.14 + 0.04
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.58 + 0.29	22.59 + 0.23	22.49 + 0.39	21.49 + 0.38
Hemoglobin Conc. Distr. Width	mmol/l	1.74 + 0.07	1.81 + 0.06	1.84 + 0.06 2.	04 + 0.13
Reticulocyte (Rel)*	rel. 1	0.021 + 0.003	0.20 + 0.002	0.021 + 0.002	0.027 + 0.02
Reticulocyte (Abs)	G/l	185 + 27	183 + 19	201 + 22	273 + 109
Maturity Index (L-Reti)*	rel. 1	0.560 + 0.034	0.644 + 0.038	0.605 + 0.030	0.610 + 0.06
Maturity Index (M-Reti)*	rel. 1	0.344 + 0.022	0.297 + 0.032	0.325 + 0.020	0.323 + 0.03
Maturity Index (H-Reti)*	rel. 1	0.094 + 0.018	0.062 + 0.13	0.070 + 0.015	0.071 + 0.026
Leukocytes, Total	G/l	11.54 + 1.28	8.45 + 1.48	9.14 + 1.15	9.46 + 3.15
Neutrophils *	rel. 1	0.149 + 0.038	0.266 + 0.079	0.189 + 0.060	0.303 + 0.05
Eosinophils *	rel. 1	0.012 + 0.006	0.020 + 0.004	0.020 + 0.004	0.023 + 0.01
Basophils *	rel. 1	0.006 + 0.001	0.006 + 0.002	0.007 + 0.002	0.003 + 0.00
Lymphocytes*	rel. 1	0.790 + 0.038	0.672 + 0.080	0.735 + 0.061	0.62 + 0.05
Monocytes*	rel. 1	0.027 + 0.005	0.025 + 0.007	0.035 + 0.006	0.051 + 0.009
Large Unstained Cells*	rel. 1	0.012 + 0.003	0.006 + 0.002	0.008 + 0.002	0.006 + 0.002
Neutrophils	G/l	1.77 + 0.48	2.28 + 0.74	1.92 + 0.73	2.79 + 0.96
Eosinophils	G/l	0.15 + 0.08	0.17 + 0.04	0.18 + 0.04	0.22 + 0.09
Basophils	G/l	0.07 + 0.02	0.05 + 0.02	0.07 + 0.02	0.03 + 0.02
Lymphocytes	G/l	9.11 + 1.16	5.66 + 1.14	6.57 + 0.76	5.94 + 2.1
Monocytes	G/l	0.31 + 0.07	0.23 + 0.09	0.32 + 0.07	0.50 + 0.25
Large Unstained Cells	G/l	0.13 + 0.04	0.06 + 0.02	0.08 + 0.02	0.06 + 0.03
Thrombocytes (Platelets)	G/l	887 + 102	798 + 109	886 + 97	886 + 145
Prothrombin Time*	rel. 1	0.89 + 0.09**	0.94 + 0.06	0.86 + 0.09	0.90 + 0.08
Partial Thromboplastin Time *	sec	27.7 + 1.9**	26.2 + 1.5	25.8 + 2.1	20.7 + 2.9

Data represents average ± one standard deviation
* Data represents median ± one standard deviation ** n = 20

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 1 FEMALES - FEED

COMPLETE BLOOD COUNT	UNITS	28 DAYS n = 19	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 29
Erythrocytes	T/l	8.35 + 0.25	8.23 + 0.21	8.36 + 0.29	7.52 + 1.0
Hemoglobin	mmol/l	9.9 + 0.3 9.	9 + 0.2	10.0 + 0.3	9.14 + 1.2
Hematocrit	rel. 1	0.43 + 0.01	0.43 + 0.01	0.44 + 0.01	0.43 + 0.05
Mean Corpuscular Volume	fl	51.8 + 1.0	51.7 + 0.7	52.7 + 0.9	57 + 2.8
Red Cell Vol. Distr. Width	rel. 1	0.108 + 0.003	0.115 + 0.003	0.113 + 0.003	0.128 + 0.02
Mean Corpuscular Hemoglobin	fmol	1.19 + 0.03	1.21 + 0.03	1.20 + 0.02	1.22 + 0.05
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.88 + 0.26	23.36 + 0.29	22.67 + 0.27	21.31 + 0.87
Hemoglobin Conc. Distr. Width	mmol/l	1.64 + 0.08	1.70 + 0.07	1.65 + 0.05	1.71 + 0.13
Reticulocyte (Rel)*	rel. 1	0.021 + 0.004	0.022 + 0.005	0.020 + 0.006	0.023 + 0.03
Reticulocyte (Abs)	G/l	188 + 33	177 + 38	182 + 47	207 + 125
Maturity Index (L-Reti)*	rel. 1	0.535 + .055	0.671 + 0.071	0.593 + 0.052	0.984 + 0.05
Maturity Index (M-Reti)*	rel. 1	0.349 + 0.022	0.293 + 0.052	0.338 + 0.033	0.016 + 0.05
Maturity Index (H-Reti)*	rel. 1	0.121 + 0.039	0.044 + 0.022	0.070 + 0.025	0.00 + 0.00
Leukocytes, Total	G/l	8.22 + 1.74	5.76 + 1.45	5.92 + 1.45	5.42 + 1.6
Neutrophils *	rel. 1	0.133 + 0.024	0.160 + 0.045	0.144 + 0.029	0.326 + 0.10
Eosinophils *	rel. 1	0.014 + 0.003	0.023 + 0.008	0.032 + 0.009	0.024 + 0.01
Basophils *	rel. 1	0.005 + 0.001	0.008 + 0.002	0.008 + 0.002	0.004 + 0.00
Lymphocytes*	rel. 1	0.810 + 0.027	0.785 + 0.048	0.773 + 0.032	0.589 + 0.10
Monocytes*	rel. 1	0.023 + 0.005	0.020 + 0.004	0.031 + 0.007	0.041 + 0.01
Large Unstained Cells*	rel. 1	0.012 + 0.004	0.005 + 0.002	0.008 + 0.002	0.008 + 0.01
Neutrophils	G/l	1.1 + 0.35	0.85 + 0.26	0.89 + 0.35	1.86 + 0.89
Eosinophils	G/l	0.12 + 0.04	0.13 + 0.05	0.19 + 0.06	0.13 + 0.05
Basophils	G/l	0.04 + 0.02	0.04 + 0.02	0.05 + 0.01	0.02 + 0.01
Lymphocytes	G/l	6.64 + 1.36	4.58 + 1.33	4.55 + 1.05	3.14 + 0.97
Monocytes	G/l	0.20 + 0.05	0.12 + 0.04	0.19 + 0.06	0.24 + 0.10
Large Unstained Cells	G/l	0.11 + 0.04	0.03 + 0.01	0.05 + 0.02	0.05 + 0.02
Thrombocytes (Platelets)	G/l	998 + 87	837 + 80	852 + 75	894 + 258
Prothrombin Time*	rel. 1	0.85 + 0.05**	0.85 + 0.07	0.84 + 0.09	0.87 + 0.10
Partial Thromboplastin Time *	sec	25.8 + 2.0**	27.2 + 1.9	29.5 + 3.3	26.2 + 3.4

Data represents average ± one standard deviation
* Data represents median ± one standard deviation ** n = 20

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 2 FEMALES - GAVAGE

COMPLETE BLOOD COUNT	UNITS	28 DAYS n = 20	13 WEEKS n = 19	26 WEEKS n = 18	104 WEEKS n = 28
Erythrocytes	T/l	8.32 + 0.27	8.16 + 0.24	8.21 + 0.27	7.92 + 0.78
Hemoglobin	mmol/l	10.0 + 0.2	9.8 + 0.3	9.8 + 0.3	9.4 + 0.81
Hematocrit	rel. 1	0.44 + 0.01	0.43 + 0.01	0.43 + 0.01	0.45 + 0.03
Mean Corpuscular Volume	fl	52.4 + 0.9	52.2 + 1.3	52.2 + 1.2	57 + 3.0
Red Cell Vol. Distr. Width	rel. 1	0.109 + 0.003	0.116 + 0.004	0.112 + 0.002	0.124 + 0.01
Mean Corpuscular Hemoglobin	fmol	1.20 + 0.02	1.20 + 0.03	1.19 + 0.03	1.19 + 0.05
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.87 + 0.19	23.05 + 0.19	22.78 + 0.24	21.06 + 0.45
Hemoglobin Conc. Distr. Width	mmol/l	1.67 + 0.07	1.67 + 0.06	1.64 + 0.06	1.71 + 0.18
Reticulocyte (Rel)*	rel. 1	0.021 + 0.005	0.025 + 0.004	0.022 + 0.003	0.02 + 0.01
Reticulocyte (Abs)	G/l	186 + 36	208 + 34	187 + 26	181 + 73
Maturity Index (L-Reti)*	rel. 1	0.524 + 0.060	0.635 + 0.050	0.593 + 0.044	0.980 + 0.02
Maturity Index (M-Reti)*	rel. 1	0.347 + 0.027	0.317 + 0.027	0.336 + 0.029	0.019 + 0.02
Maturity Index (H-Reti)*	rel. 1	0.133 + 0.037	0.051 + 0.025	0.066 + 0.024	0.00 + 0.00
Leukocytes, Total	G/l	8.09 + 1.74	4.76 + 1.14	5.42 + 1.24	5.44 + 1.9
Neutrophils *	rel. 1	0.116 + 0.026	0.127 + 0.036	0.161 + 0.036	0.351 + 0.09
Eosinophils *	rel. 1	0.016 + 0.005	0.023 + 0.007	0.024 + 0.006	0.024 + 0.01
Basophils *	rel. 1	0.005 + 0.001	0.007 + 0.003	0.008 + 0.002	0.005 + 0.001
Lymphocytes*	rel. 1	0.823 + 0.027	0.821 + 0.039	0.764 + 0.037	0.576 + 0.10
Monocytes*	el. 1	0.026 + 0.005	0.020 + 0.007	0.027 + 0.007	0.043 + 0.01
Large Unstained Cells*	rel. 1	0.013 + 0.003	0.005 + 0.002	0.008 + 0.002	0.008 + 0.004
Neutrophils	G/l	0.95 + 0.25	0.65 + 0.27	0.93 + 0.38	2.04 + 1.32
Eosinophils	G/l	0.13 + 0.05	0.11 + 0.04	0.14 + 0.04	0.13 + 0.05
Basophils	G/l	0.04 + 0.02	0.03 + 0.02	0.04 + 0.01	0.02 + 0.01
Lymphocytes	G/l	6.65 + 1.48	3.84 + 0.91	4.11 + 0.88	2.95 + 0.63
Monocytes	G/l	0.21 + 0.08	0.11 + 0.04	0.15 + 0.06	0.24 + 0.14
Large Unstained Cells	G/l	0.10 + 0.04	0.03 + 0.01	0.05 + 0.01	0.05 + 0.04
Thrombocytes (Platelets)	G/l	1022 + 96	865 + 96	916 + 100	885 + 201
Prothrombin Time*	rel. 1	0.88 + 0.05	0.89 + 0.07	0.86 + 0.06**	0.94 + 0.12
Partial Thromboplastin Time *	sec	25.5 + 2.0	27.2 + 2.1	28.9 + 4.7**	26.2 + 2.9

Data represents average ± one standard deviation
* Data represents median ± one standard deviation ** n = 19

Hsd:Sprague Dawley® SD®

STUDY C11963 | COMPLETE BLOOD COUNT REFERENCE RANGES

GROUP 1 MALES - FEED	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Erythrocytes	T/l	8.41 - 9.51	8.8 - 10.25	8.97 - 10.75	7.32 - 9.79
Hemoglobin	mmol/l	10.0 - 11.0	10.1 - 11.1	10.3 - 11.7	8.7 - 10.7
Hematocrit	rel. 1	0.45 - 0.50	0.44 - 0.50	0.45 - 0.53	0.41 - 0.50
Mean Corpuscular Volume	fl	50.2 - 56.7	47.6 - 51.9	49.2 - 51.8	50.7 - 56.6
Red Cell Vol. Distr. Width	rel. 1	0.105 - 0.116	0.119 - 0.128	0.121 - 0.130	0.124 - 0.145
Mean Corpuscular Hemoglobin	fmol	1.13 - 1.25	1.06 - 1.17	1.08 - 1.17	1.05 - 1.25
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.09 - 22.8	22.15 - 23.02	21.87 - 23.28	20.63 - 22.44
Hemoglobin Conc. Distr. Width	mmol/l	1.57 - 1.80	1.72 - 1.96	1.72 - 1.97	1.89 - 2.32
Reticulocyte (Rel)	rel. 1	0.018 - 0.033	0.016 - 0.002	0.017 - 0.025	0.02 - 0.042
Reticulocyte (Abs)	G/l	165 - 287	149 - 205	158 - 234	171 - 321
Maturity Index (L-Reti)	rel. 1	0.439 - 0.601	0.630 - 0.727	0.524 - 0.657	0.476 - 0.754
Maturity Index (M-Reti)	rel. 1	0.318 - 0.383	0.222 - 0.307	0.277 - 0.367	0.209 - 0.386
Maturity Index (H-Reti)	rel. 1	0.062 - 0.196	0.016 - 0.78	0.054 - 0.114	0.037 - 0.142
Leukocytes, Total	G/l	9.52 - 16.11	6.61 - 11.25	8.19 - 14.05	5.53 - 19.2
Neutrophils	rel. 1	0.079 - 0.273	0.116 - 0.340	0.123 - 0.457	0.196 - 0.523
Eosinophils	rel. 1	0.006 - 0.019	0.011 - 0.023	0.016 - 0.038	0.009 - 0.035
Basophils	rel. 1	0.005 - 0.008	0.003 - 0.010	0.005 - 0.011	0.001 - 0.005
Lymphocytes	rel. 1	0.665 - 0.860	0.599 - 0.841	0.468 - 0.808	0.403 - 0.723
Monocytes	rel. 1	0.020 - 0.046	0.015 - 0.045	0.0.31 -0.058	0.024 - 0.063
Large Unstained Cells	rel. 1	0.007 - 0.025	0.003 - 0.009	0.004 - 0.013	0.003 - 0.008
Neutrophils	G/l	0.83 - 3.61	1.03 - 3.61	1.09 - 6.42	1.31 - 9.74
Eosinophils	G/l	0.07 - 0.21	0.12 - 0.24	0.15 - 0.36	0.14 - 0.42
Basophils	G/l	0.06 - 0.13	0.02 - 0.11	0.05 - 0.15	0.01 - 0.06
Lymphocytes	G/l	6.75 - 13.66	4.23 - 8.14	5.74 - 9.40	3.81 - 8.37
Monocytes	G/l	0.22 - 0.64	0.13 - 0.44	0.30 - 0.55	0.13 - 1.2
Large Unstained Cells	G/l	0.09 - 0.26	0.03- 0.09	0.05 - 0.13	0.02 - 0.13
Thrombocytes (Platelets)	G/l	702 - 1032	619 - 983	664 - 1083	708 - 1416
Prothrombin Time	rel. 1	0.76 - 0.96	0.73 - 0.95	0.68 - 1.13	0.75 - 1.08
Partial Thromboplastin Time	sec	23.5 - 30.5	24.6 - 29.7	21.7 - 29.9	16.1 - 24.6

GROUP 2 MALES - GAVAGE	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Erythrocytes	T/l	8.35 - 9.30	8.9 - 9.92	8.77 - 10.23	6.52 - 10.13
Hemoglobin	mmol/l	10.0 - 10.7	9.9 - 11.0	10.2 - 11.4	7.7 - 11.0
Hematocrit	rel. 1	0.43 - 0.48	0.44 - 0.49	0.45 - 0.51	0.38 -0.52
Mean Corpuscular Volume	fl	59.7 - 54	47.1 - 52.1	49.0 - 52.2	50.6 - 58.2
Red Cell Vol. Distr. Width	rel. 1	0.107 - 0.117	0.118 - 0.130	0.117 - 0.130	0.123 - 0.16
Mean Corpuscular Hemoglobin	fmol	1.12 - 1.22	1.06 - 1.18	1.10 - 1.21	1.08 - 1.20
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.05 - 23.44	22.15 - 23.08	22.01 - 23.72	20.4 - 22.41
Hemoglobin Conc. Distr. Width	mmol/l	1.63 - 1.84	1.73 - 1.98	1.73 - 1.95	1.75 - 2.33
Reticulocyte (Rel)	rel. 1	0.017 - 0.028	0.014 - 0.025	0.016 - 0.026	0.019 - 0.108
Reticulocyte (Abs)	G/l	149 - 241	135 - 228	154 - 252	166-702
Maturity Index (L-Reti)	rel. 1	0.504 - 0.642	0.592 - 0.717	0.559 - 0.664	0.188 - 0.767
Maturity Index (M-Reti)	rel. 1	0.293 - 0.385	0.239 - 0.336	0.283 - 0.352	0.206 - 0.394
Maturity Index (H-Reti)	rel. 1	0.065 - 0.140	0.038 - 0.089	0.053 - 0.106	0.021 - 0.146
Leukocytes, Total	G/l	9.58 - 14.89	5.72 - 11.17	7.46 - 11.21	3.41 - 14.04
Neutrophils	rel. 1	0.097 - 0.228	0.154 - 0.475	0.118 - 0.326	0.196 - 0.382
Eosinophils	rel. 1	0.009 - 0.037	0.013 - 0.027	0.014 - 0.026	0.013 - 0.035
Basophils	rel. 1	0.004 - 0.008	0.004 - 0.010	0.004 - 0.011	0.001 - 0.005
Lymphocytes	rel. 1	0.712 - 0.846	0.468 - 0.797	0.584 - 0.822	0.531 - 0.736
Monocytes	rel. 1	00.019 - 0.038	0.019 - 0.044	0.024 - 0.050	0.027 - 0.075
Large Unstained Cells	rel. 1	0.007 - 0.018	0.004 - 0.010	0.003 - 0.013	0.002 - 0.011
Neutrophils	G/l	1.13 - 3.08	1.01 - 3.52	0.99 - 3.46	1.22 - 4.20
Eosinophils	G/l	0.09 - 0.48	0.10 - 0.29	0.14 - 0.24	0.07 - 0.41
Basophils	G/l	0.04 - 0.10	0.03 - 0.12	0.03 - 0.10	0.01 - 0.06
Lymphocytes	G/l	7.44 - 12.44	3.47 - 8.15	5.11 - 8.37	1.81 - 10.01
Monocytes	G/l	0.20 - 0.42	0.11 - 0.49	0.20 - 0.44	0.17 - 0.88
Large Unstained Cells	G/l	0.07 - 0.19	0.03 - 0.11	0.03 - 0.11	0.02 - 0.14
Thrombocytes (Platelets)	G/l	714 - 1156	666 - 1013	725 - 1143	615 - 1270
Prothrombin Time	rel. 1	0.74 - 1.16	0.76 - 1.09	0.75 - 1.09	0.70 - 1.04
Partial Thromboplastin Time	sec	23.6 - 32.5	23.0 - 27.9	23.1 - 29.9	13.6 - 24.3

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STUDY C11963 | COMPLETE BLOOD COUNT REFERENCE RANGES

GROUP 1 FEMALES - FEED	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Erythrocytes	T/l	8.00 - 8.93	7.83 - 8.58	7.92 - 9.13	4.91 - 9.65
Hemoglobin	mmol/l	9.3 - 10.4	9.5 - 10.5	9.6 - 10.7	6.2 - 11.9
Hematocrit	rel. 1	0.42 - 0.45	0.41 - 0.45	0.43 - 0.48	0.32 - 0.55
Mean Corpuscular Volume	fl	50.1 - 53.4	50.3 - 53.3	50.6 - 54.5	52.6 - 67.3
Red Cell Vol. Distr. Width	rel. 1	0.103 - 0.113	0.109 - 0.122	0.106 - 0.120	0.118 - 0.186
Mean Corpuscular Hemoglobin	fmol	1.11 - 1.24	1.17 - 1.28	1.15 - 1.25	1.15 - 1.38
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.18 - 23.5	22.92 - 23.94	22.27 - 23.07	18.72 - 23.7
Hemoglobin Conc. Distr. Width	mmol/l	1.52 - 1.89	1.60 - 1.82	1.55 - 1.74	1.50 - 2.11
Reticulocyte (Rel)	rel. 1	0.017 - 0.032	0.014 - 0.033	0.010 - 0.033	0.009 - 0.11
Reticulocyte (Abs)	G/l	150 - 261	115 - 263	86 - 273	77 - 552
Maturity Index (L-Reti)	rel. 1	0.446 - 0.645	0.545 - 0.766	0.520 -0.706	0.728 - 0.998
Maturity Index (M-Reti)	rel. 1	0.293 - 0.376	0.195 - 0.375	0.262 - 0.370	0.002 - 0.267
Maturity Index (H-Reti)	rel. 1	0.062 - 0.204	0.018 - 0.093	0.031 - 0.129	0 - 0.006
Leukocytes, Total	G/l	5.49 - 13.63	3.02 - 8.38	3.23 - 9.60	2.56 - 10.16
Neutrophils	rel. 1	0.086 - 0.166	0.079 - 0.207	0.094 - 0.203	0.165 - 0.569
Eosinophils	rel. 1	0.010 - 0.021	0.013 - 0.045	0.018 - 0.047	0.01 - 0.055
Basophils	rel. 1	0.003 - 0.007	0.003 - 0.012	0.006 - 0.012	0.002 - 0.02
Lymphocytes	rel. 1	0.771 - 0.856	0.662 - 0.876	0.710 - 0.831	0.334 - 0.730
Monocytes	rel. 1	0.017 - 0.034	0.012 - 0.030	0.022 - 0.045	0.026 - 0.069
Large Unstained Cells	rel. 1	0.008 - 0.021	0.003 - 0.009	0.005 - 0.014	0.004 - 0.032
Neutrophils	G/l	0.67 - 2.23	0.57 - 1.48	0.42 - 1.89	0.42 - 4.27
Eosinophils	G/l	0.07 - 0.26	0.08 - 0.23	0.08 - 0.29	0.03 - 0.23
Basophils	G/l	0.02 - 0.09	0.02 - 0.08	0.03 - 0.08	0.01 - 0.05
Lymphocytes	G/l	4.5 - 10.6	2.25 - 7.34	2.60 - 7.01	1.87 - 5.98
Monocytes	G/l	0.10 - 0.30	0.05 - 0.19	0.08 - 0.31	0.11 - 0.48
Large Unstained Cells	G/l	0.06 - 0.18	0.01 - 0.06	0.02 - 0.08	0.02 - 0.12
Thrombocytes (Platelets)	G/l	806 - 1157	681 - 1003	673 - 1002	398 - 1739
Prothrombin Time	rel. 1	0.72 - 0.94	0.69 - 0.95	0.66 - 1.04	0.71 - 1.06
Partial Thromboplastin Time	sec	21.8 - 28.6	23.3 - 31.7	25.0 - 36.7	20 - 32.4

GROUP 2 FEMALES - GAVAGE	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Erythrocytes	T/l	7.9 - 8.79	7.36 - 8.49	7.61 - 8.81	5.03 - 8.93
Hemoglobin	mmol/l	9.4 - 10.4	9.3 - 10.2	9.3 - 10.2	6.8 - 10.6
Hematocrit	rel. 1	0.41 - 0.46	0.40 - 0.44	0.40 - 0.45	0.34 - 0.48
Mean Corpuscular Volume	fl	50.3 - 23.5	49.5 - 54.5	49.5 - 54.1	51 - 68.4
Red Cell Vol. Distr. Width	rel. 1	0.104 - 0.115	0.111 - 0.127	0.108 - 0.115	0.115 - 0.146
Mean Corpuscular Hemoglobin	fmol	1.16 - 1.23	1.13 - 1.27	1.14 - 1.24	1.06 - 1.36
Mean Corpuscular Hemoglobin Conc.	mmol/l	22.54 - 23.15	22.75 - 23.36	22.17 - 23.15	19.89 - 22.2
Hemoglobin Conc. Distr. Width	mmol/l	1.54 - 1.78	1.57 - 1.77	1.53 - 1.74	1.38 - 2.26
Reticulocyte (Rel)	rel. 1	0.015 - 0.034	0.017 - 0.034	0.018 - 0.028	0.011 - 0.089
Reticulocyte (Abs)	G/l	128 - 273	143 - 278	141 - 230	89 - 447
Maturity Index (L-Reti)	rel. 1	0.431 - 0.630	0.531 - 0.675	0.517 - 0.687	0.889 - 0.997
Maturity Index (M-Reti)	rel. 1	0.288 - 0.391	0.287 - 0.366	0.254 - 0.368	0.003 - 0.11
Maturity Index (H-Reti)	rel. 1	0.071 - 0.188	0.037 - 0.110	0.046 - 0.133	0 - 0.002
Leukocytes, Total	G/l	4.85 - 12.78	3.16 - 7.12	3.97 - 9.05	3.28 - 11.24
Neutrophils	rel. 1	0.065 - 0.168	0.079 - 0.207	0.115 - 0.263	0.165 - 0.573
Eosinophils	rel. 1	0.009 - 0.029	0.012 - 0.038	0.016 - 0.039	0.009 - 0.048
Basophils	rel. 1	0.003 - 0.007	0.004 - 0.015	0.005 - 0.010	0.001 - 0.008
Lymphocytes	rel. 1	0.774 - 0.886	0.734 - 0.871	0.672 - 0.824	0.337 - 0.777
Monocytes	rel. 1	0.019 - 0.037	0.015 - 0.042	0.014 - 0.038	0.024 - 0.067
Large Unstained Cells	rel. 1	0.008 - 0.020	0.003 - 0.009	0.006 - 0.014	0.003 - 0.022
Neutrophils	G/l	0.54 - 1.48	0.28 - 1.34	0.54 - 2.38	0.74 - 6.17
Eosinophils	G/l	0.07 - 0.24	0.05 - 0.20	0.08 - 0.21	0.07 - 0.38
Basophils	G/l	0.02 - 0.08	0.01 - 0.07	0.02 - 0.06	0 - 0.06
Lymphocytes	G/l	4.04 - 10.53	2.48 - 5.67	2.84 - 6.08	1.82 - 4.31
Monocytes	G/l	0.08 - 0.42	0.05 - 0.20	0.07 - 0.26	0.09 - 0.76
Large Unstained Cells	G/l	0.06 - 0.23	0.01 - 0.05	0.03 - 0.07	0.02 - 0.24
Thrombocytes (Platelets)	G/l	807 - 1224	713 - 1031	792 - 1179	599 - 1523
Prothrombin Time	rel. 1	0.79 - 1.02	0.71 - 1.05	0.75 - 0.97	0.73 - 1.15
Partial Thromboplastin Time	sec	21.4 - 28.2	23.0 - 30.8	23.1 - 41.3	22.3 - 33.2

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STUDY C11963 | GROUP 1 MALES - FEED

SERUM CHEMISTRY	UNITS	28 DAYS n = 20	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 19
Glucose	mmol/l	4.86 + 0.39	6.48 + 0.61	5.65 + 0.95	6.09 + 1.31
Urea	mmol/l	6.47 + 0.64	6.29 + 0.60	6.65 + 1.27	6.88 + 2.70
Creatinine	µmol/l	26.7 + 2.50	29.2 + 2.50	32.1 + 4.20	43.9 + 18.7
Total Bilirubin	µmol/l	1.5 + 0.28	1.74 + 1.50	2.17 + 1.13	1.87 + 0.45
Cholesterol	mmol/l	2.61 + 0.27	2.70 + 0.31	2.79 + 0.43	7.40 + 1.56
Triglycerides	mmol/l	0.36 + 0.10	0.45 + 0.17	0.84 + 0.36	1.21 + 0.66
Phospholipids	mmol/l	1.74 + 0.13	1.84 + 0.27	1.46 + 0.16	3.91 + 0.65
ASAT	U/l	89.5 + 12.0	74.5 + 7.60	85.1 + 51.7	66.2 + 16.0
ALAT	U/l	40.6 + 7.0	40.2 + 5.00	70.7 + 114.4	36.9 + 12.5
LDH	U/l	197.3 + 47.1	136.1 + 37.8	194.9 + 83.9	156.1 + 52.1
GLDH	U/l	2.5 + 1.8*	3.4 + 1.3**	2.7 + 1.0†	9.7 + 13.4
ALP	U/l	100.9 + 9.70	62.6 + 8.90	126.5 + 309.8	52.0 + 15.9
GGT	U/l	0	0	0.12 + 0.5	0.30 + 1.4
Creatine Kinase	U/l	211.5 + 130.3	148.8 + 70.7	149.4 + 94.6	136.8 + 75.3
Sodium	mmol/l	144.8 + 0.80	143.5 + 1.10	143.1 + 1.10	147.1 + 1.40
Potassium	mmol/l	3.73 + 0.18	4.04 + 0.23	4.07 + 0.32	3.76 + 0.22
Chloride	mmol/l	100.1 + 1.00	103.2 + 1.00	101.9 + 1.10	104.6 + 1.62
Calcium	mmol/l	2.65 + 0.06	2.67 + 0.05	2.67 + 0.05	2.75 + 0.07
Phosphorus	mmol/l	2.31 + 0.15	1.87 + 0.11	1.69 + 0.14	1.41 + 0.14
Protein	g/l	71.16 + 1.67	71.61 + 2.24	71.85 + 2.41	72.61 + 2.77
Albumin	g/l	42.24 + 0.74	40.43 + 1.08	40.11 + 1.64	34.01 + 2.97

Data represents average ± one standard deviation
* n = 8 ** n = 14 † n = 12

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 2 MALES - GAVAGE

SERUM CHEMISTRY	UNITS	28 DAYS n = 20	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 21
Glucose	mmol/l	5.51 + 0.62	5.16 + 0.50	6.08 + 0.87	5.88 + 1.12
Urea	mmol/l	7.00 + 0.79	6.42 + 0.52	6.20 + 0.57	7.68 + 5.53
Creatinine	µmol/l	27.0 + 3.00	31.1 + 2.20	29.7 + 2.70	45.7 + 25.7
Total Bilirubin	µmol/l	1.15 + 0.34	1.71 + 0.41	1.96 + 0.26	1.87 + 0.34
Cholesterol	mmol/l	2.57 + 0.28	2.71 + 0.30	2.76 + 0.48	7.18 + 1.45
Triglycerides	mmol/l	0.28 + 0.06	0.38 + 0.12	0.62 + 0.26	1.10 + 0.50
Phospholipids	mmol/l	1.64 + 0.13	1.85 + 0.27	1.46 + 0.21	3.88 + 0.59
ASAT	U/l	87.7 + 11.1	75.8 + 6.90	72.6 + 12.4	56.8 + 13.4
ALAT	U/l	38.3 + 3.70	39.2 + 5.20	46.8 + 6.60	33.1 + 6.30
LDH	U/l	171.3 + 42.2	158.2 + 35.9	138.0 + 51.0	113.8 + 24.5
GLDH	U/l	2.7 + 1.7*	3.6 + 0.9*	3.0 + 1.0**	6.98 + 5.13
ALP	U/l	97.7 + 14.8	68.9 + 8.90	60.8 + 11.4	50.6 + 11.9
GGT	U/l	0	0	0	0.10 + 0.48
Creatine Kinase	U/l	195.5 + 94.1	141.6 + 39.1	117.0 + 27.7	93.3 + 25.0
Sodium	mmol/l	146.1 + 1.00	146.0 + 1.20	144.1 + 0.90	147.6 + 1.43
Potassium	mmol/l	3.74 + 0.19	4.13 + 0.17	4.1 + 0.19	3.74 + 0.32
Chloride	mmol/l	101.7 + 1.00	104.8 + 1.20	103.3 + 0.80	104.8 + 1.40
Calcium	mmol/l	2.61 + 0.05	2.68 + 0.06	2.67 + 0.05	2.66 + 0.51
Phosphorus	mmol/l	2.27 + 0.12	1.78 + 0.08	1.73 + 0.10	1.52 + 0.29
Protein	g/l	68.88 + 1.63	73.04 + 2.24	70.85 + 2.03	73.0 + 2.50
Albumin	g/l	41.34 + 0.81	41.06 + 0.79	40.24 + 1.15	34.7 + 3.11

Data represents average ± one standard deviation
* n = 14 ** n = 13

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 1 FEMALES - FEED

SERUM CHEMISTRY	UNITS	28 DAYS n = 20	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 29
Glucose	mmol/l	5.18 + 0.40	6.04 + 0.60	6.12 + 0.74	6.02 + 1.48
Urea	mmol/l	6.47 + 0.62	7.02 + 0.75	7.42 + 1.06	5.98 + 2.8
Creatinine	µmol/l	32.9 + 3.30	40.7 + 3.90	41.4 + 4.00	29.6 + 4.9
Total Bilirubin	µmol/l	1.56 + 0.49	2.44 + 0.47	3.33 + 0.92	6.99 + 6.14
Cholesterol	mmol/l	2.53 + 0.44	2.80 + 0.50	2.99 + 0.56	4.56 + 1.18
Triglycerides	mmol/l	0.22 + 0.06	0.28 + 0.05	0.33 + 0.09	0.90 + 0.97
Phospholipids	mmol/l	1.81 + 0.31	2.19 + 0.31	1.84 + 0.32	3.33 + 0.67
ASAT	U/l	88.0 + 7.80	79.4 + 8.00	75.1 + 12.1	74.1 + 25.4
ALAT	U/l	31.7 + 4.50	30.8 + 8.40	32.6 + 6.70	31.4 + 7.11
LDH	U/l	227.9 + 51.1	121.5 + 35.8	167.0 + 60.0	155.6 + 76.9
GLDH	U/l	2.3 + 0.80*	2.8 + 1.4	3.3 + 4.3	10.4 + 14.0
ALP	U/l	78.2 + 10.9	50.4 + 14.1	39.3 + 9.60	25.8 + 9.63
GGT	U/l	0	0	0	0
Creatine Kinase	U/l	186.2 + 54.2	128.2 + 38.3	144.6 + 101.7	102.1 + 35.7
Sodium	mmol/l	145.8 + 0.90	147.0 + 1.60	143.8 + 1.20	143.5 + 1.43
Potassium	mmol/l	3.56 + 0.14	3.75 + 0.19	3.75 + 0.20	3.63 + 0.34
Chloride	mmol/l	102.7 + 1.10	108.6 + 1.4	105.1 + 1.40	103.0 + 1.60
Calcium	mmol/l	2.63 + 0.04	2.65 + 0.06	2.69 + 0.05	2.68 + 0.08
Phosphorus	mmol/l	2.09 + 0.12	1.66 + 0.14	1.51 + 0.19	1.30 + 0.21
Protein	g/l	68.45 + 1.49	70.24 + 2.48	72.02 + 2.45	73.5 + 3.81
Albumin	g/l	43.68 + 1.44	44.81 + 2.40	47.04 + 1.89	45.2 + 3.76

Data represents average ± one standard deviation
* n = 12

Hsd:Sprague Dawley® SD®

STUDY C11963 | GROUP 2 FEMALES - GAVAGE

SERUM CHEMISTRY	UNITS	28 DAYS N = 20	13 WEEKS N = 19	26 WEEKS N = 19	104 WEEKS N = 28
Glucose	mmol/l	5.3 + 0.33	5.8 + 0.63	6.98 + 0.74	6.47 + 1.63
Urea	mmol/l	6.69 + 0.76◊	7.22 + 0.72	7.59 + 0.98	5.91 + 1.55
Creatinine	µmol/l	32.1 + 3.50	39.8 + 3.30	41.0 + 3.80	31.5 + 6.70
Total Bilirubin	µmol/l	1.39 + 0.20◊	2.93 + 0.58*	2.66 + 0.57	14.2 + 1.54
Cholesterol	mmol/l	2.59 + 0.36	3.08 + 0.43	3.09 + 0.52	5.04 + 1.52
Triglycerides	mmol/l	0.25 + 0.08	0.29 + 0.04	0.29 + 0.05	0.86 + 0.56
Phospholipids	mmol/l	1.86 + 0.27*	2.52 + 0.33*	1.91 + 0.31	3.68 + 0.90
ASAT	U/l	84.9 + 6.10◊	78.4 + 8.10	75.6 + 14.6	70.9 + 25.2
ALAT	U/l	29.6 + 3.70	30.1 + 4.0	35.2 + 4.80	34.1 + 16.1
LDH	U/l	189.3 + 56.5	180.3 + 46.2	138.1 + 34.4	160.4 + 83.5
GLDH	U/l	1.7 + 0.7‡	2.4 + 1.2**	3.1 + 2.3†	10.4 + 15.6
ALP	U/l	72.1 + 7.10*	44.8 + 5.80	39.9 + 7.40	34.4 + 61.3
GGT	U/l	0	0	0	0.59 + 3.10
Creatine Kinase	U/l	171.5 + 32.8	155.1 + 70.8	116.1 + 83.0	134.4 + 80.0
Sodium	mmol/l	144.2 + 1.10	150.0 + 1.10	145.2 + 1.30	143.3 + 1.44
Potassium	mmol/l	3.67 + 0.17◊	4.01 + 0.27	3.95 + 0.15	3.56 + 0.45
Chloride	mmol/l	102.3 + 1.30◊	111.5 + 2.0	107.2 + 1.30	101.2 + 4.12
Calcium	mmol/l	2.63 + 0.04◊	2.72 + 0.05	2.68 + 0.05	2.72 + 0.09
Phosphorus	mmol/l	2.08 + 0.18	1.57 + 0.17	1.47 + 0.20	1.37 + 0.22
Protein	g/l	66.67 + 1.65	72.78 + 2.34	75.00 + 3.88	75.1 + 4.58
Albumin	g/l	43.06 + 0.98*	45.09 + 3.67	48.3 + 3.37	45.7 + 4.95

Data represents average ± one standard deviation
† n = 15 ‡ n = 10 * n = 18 ** n = 12 ◊ n = 19

Hsd:Sprague Dawley® SD®

STUDY C11963 | SERUM CHEMISTRY REFERENCE RANGES

GROUP 1 MALES - FEED	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Glucose	mmol/l	4.07 - 5.7	5.46 - 7.75	4.31 - 8.7	2.72 - 8.91
Urea	mmol/l	5.53 - 7.81	5.15 - 7.46	4.98 - 10.77	3.79 - 14.46
Creatinine	µmol/l	22.1 - 30.8	23.9 - 33.1	26 - 43.1	24.5 - 90.4
Total Bilirubin	µmol/l	1.04 - 2.02	1.5 - 2.26	1.32 - 6.08	1.04 - 2.73
Cholesterol	mmol/l	2.11 - 3.29	2.08 - 3.21	2.14 - 3.71	4.69 - 10.82
Triglycerides	mmol/l	0.19 - 0.65	0.17 - 0.96	0.27 - 1.72	0.6 - 3.31
Phospholipids	mmol/l	1.46 - 1.94	0.89 - 2.11	1.11 - 1.73	2.75 - 5.28
ASAT	U/l	74.3 - 114.1	60.5 - 94.8	62 - 301.4	51.1 - 108.2
ALAT	U/l	26.2 - 57.4	30.1 - 48.5	36.9 - 556.4	24.3 - 82.4
LDH	U/l	130.6 - 286.7	77.5 - 210.9	91 - 381.1	81.9 - 279.9
GLDH	U/l	1.0 - 6.5	1.5 - 6.2	0.8 - 4.6	1.1 - 51.1
ALP	U/l	86.1 - 120	50.0 - 81.0	45.7 - 1442.5	30.2 - 91.2
GGT	U/l	0 - 0	0 - 0	0 - 2.3	0 - 6.1
Creatine Kinase	U/l	133.2 - 653.1	88.1 - 412.1	81.8 - 516.9	66.3 - 373.7
Sodium	mmol/l	143.3 - 146.6	141.5 - 145.1	140.9 - 145.2	144.9 - 149.6
Potassium	mmol/l	3.27 - 4.04	3.74 - 4.49	3.66 - 4.72	3.32 - 4.28
Chloride	mmol/l	98.2 - 103.2	101.6 - 105.4	98. 3 - 103.3	100.8 - 107.2
Calcium	mmol/l	2.57 - 2.77	2.57 - 2.75	2.59 - 2.77	2.64 - 2.88
Phosphorus	mmol/l	2.14 - 2.63	1.7 - 2.08	1.51 - 1.97	1.19 - 1.67
Protein	g/l	67.2 - 73.86	67.18 - 75.55	68.73 - 76.56	65.4 - 77.7
Albumin	g/l	40.78 - 43.92	37.65 - 42.04	36.22 - 41.94	28.4 - 38.8

GROUP 2 MALES - GAVAGE	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Glucose	mmol/l	4.60 - 7.0	4.30 - 6.4	4.79 - 8.96	2.2 - 7.23
Urea	mmol/l	6.05 - 8.16	5.2 - 7.34	5.02 - 7.29	4.16 - 29.54
Creatinine	µmol/l	23.6 - 36.1	25.8 - 33.9	23.3 - 34.7	23.4 - 121.2
Total Bilirubin	µmol/l	0.75 - 2.05	1.27 - 2.52	1.51 - 2.44	1.45 - 2.76
Cholesterol	mmol/l	2.07 - 3.23	2.18 - 3.48	2.09 - 4.18	4.79 - 9.66
Triglycerides	mmol/l	0.15 - 0.38	0.17 - 0.71	0.33 - 1.28	0.44 - 2.59
Phospholipids	mmol/l	1.44 - 1.96	0.98 - 2.33	1.18 - 2.12	2.88 - 4.87
ASAT	U/l	65.6 - 108.6	65.1 - 94.2	57 - 114.4	18.2 - 77
ALAT	U/l	30.2 - 46.4	29.4 - 49.1	35.7 - 68.7	7.3 - 47.1
LDH	U/l	117 - 266.8	106.3 - 270.8	69.6 - 303.9	73.5 - 164.8
GLDH	U/l	1.3 - 8.3	2.3 - 5.8	1.7 - 5.6	0.9 - 17.8
ALP	U/l	65.2 - 135.6	55.8 - 96.7	42.4 - 89.8	31.5 - 81.9
GGT	U/l	0 - 0	0 - 0	0 - 0	0 - 2.2
Creatine Kinase	U/l	122.4 - 535.6	96.6 - 233.1	79.3 - 163.8	56.3 - 146.7
Sodium	mmol/l	143.2 - 147.4	144.1 - 148.2	142.3 - 145.4	39.3 - 152
Potassium	mmol/l	3.33 - 4.00	3.84 - 4.41	3.71 - 4.46	3.04 - 4.58
Chloride	mmol/l	99.2 - 103	102.7 - 106.7	101.7 - 104.7	23.7 - 108.9
Calcium	mmol/l	2.5 - 2.71	2.54 - 2.82	2.58 - 2.75	0.48 - 2.97
Phosphorus	mmol/l	2.08 - 2.48	1.66 - 2.01	1.56 - 1.89	1.24 - 2.48
Protein	g/l	66.51 - 72.03	69.46 - 78.36	67.27 - 74.24	68.6 - 77.8
Albumin	g/l	39.89 - 43.01	39.66 - 43.51	38.55 - 42.46	29.7 - 40.1

Hsd:Sprague Dawley® SD®

STUDY C11963 | SERUM CHEMISTRY REFERENCE RANGES

GROUP 1 FEMALES - FEED	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Glucose	mmol/l	4.52 - 5.80	5.17 - 7.33	4.99 - 7.43	3.45 - 10.82
Urea	mmol/l	5.44 - 7.99	5.73 - 8.54	5.81 - 10.36	4.35 - 20.04
Creatinine	µmol/l	26.1 - 39.4	33.3 - 51.6	36.2 - 51.1	22.6 - 47.6
Total Bilirubin	µmol/l	0.96 - 3.25	1.91 - 4.01	2.17 - 4.89	2.59 - 36.18
Cholesterol	mmol/l	1.73 - 3.58	2.04 - 4.22	2.26 - 4.44	3.06 - 8.67
Triglycerides	mmol/l	0.16 - 0.41	0.20 - 0.44	0.21 - 0.58	0.31 - 5.53
Phospholipids	mmol/l	1.22 - 2.42	1.4 - 2.84	1.41 - 2.65	2.35 - 5.55
ASAT	U/l	74.3 - 99.9	69.1 - 97.4	64.7 - 112.6	40.3 - 159.5
ALAT	U/l	24.9 - 39.2	23. 5 - 63.2	24.1 - 49.6	19.3 - 49.7
LDH	U/l	135.6 - 326.8	78.5 - 217.5	86.3 - 334.5	75.9 - 381.2
GLDH	U/l	1.4 - 3.9	1.1 - 7.2	1.3 - 187	1.1 - 59
ALP	U/l	64.8 - 133.6	36. 2 - 100.9	26.2 - 61.7	11.2 - 52.8
GGT	U/l	0 - 0	0 - 0	0 - 0	0 - 0
Creatine Kinase	U/l	132.8 - 360.	0 74.5 - 222.1	87.5 - 558.9	53 - 191.1
Sodium	mmol/l	143.5 - 147.6	144.2 - 149.9	141.8 - 145.6	141.3 - 148.6
Potassium	mmol/l	3.36 - 3.87	3.42 - 4.06	3.42 - 4.17	2.92 - 4.64
Chloride	mmol/l	100.5 - 104.8	106.6 - 112.4	102.6 - 107.7	100 - 106.2
Calcium	mmol/l	2.55 - 2.73	2.55 - 2.78	2.60 - 2.81	2.53 - 2.86
Phosphorus	mmol/l	1.85 - 2.34	1.38 - 1.96	1.14 - 1.79	0.89 - 1.93
Protein	g/l	65.65 - 71.26	65.45 - 75.39	66.67 - 75.78	65.35 - 80.55
Albumin	g/l	41.11 - 46.98	40.09 - 51.32	44.07 - 51.34	31.87 - 49.84

GROUP 2 FEMALES - GAVAGE	UNITS	28 DAYS	13 WEEKS	26 WEEKS	104 WEEKS
Glucose	mmol/l	4.82 - 6.21	4.26 - 7.06	6.03 - 8.53	3.59 - 9.87
Urea	mmol/l	5.51 - 8.23	6.34 - 8.84	5.78 - 9.59	3.98 - 9.06
Creatinine	µmol/l	23.1 - 38.6	32.1 - 47.2	34.3 - 49.9	21.9 - 50.6
Total Bilirubin	µmol/l	0.92 - 1.69	1.7 - 3.76	1.87 - 3.96	10.58 -16.43
Cholesterol	mmol/l	1.80 - 3.46	2.46 - 3.90	2.2 - 4.0	2.51 - 7.98
Triglycerides	mmol/l	0.13 - 0.46	0.21 - 0.39	0.21 - .0.38	0.41 - 2.72
Phospholipids	mmol/l	1.38 - 2.45	1.98 - 3.12	1.43 - 2.40	2.27 - 5.33
ASAT	U/l	73.1 - 96.8	65 - 94.2	62.2 - 131.6	38.4 - 146
ALAT	U/l	23.2 - 36.6	20.9 - 36.4	27.3 - 44.1	18.3 - 105.6
LDH	U/l	92.7 - 312.2	104 - 289.3	87.5 - 222.4	90.1 - 510.4
GLDH	U/l	0.7 - 3.1	1.0 - 5.5	0.8 - 8.2	1.3 - 74.4
ALP	U/l	54.6 - 83.7	29. 4 - 54.5	28.9 - 55.7	11.8 - 348.3
GGT	U/l	0 - 0	0 - 0	0 - 0	0 - 16.4
Creatine Kinase	U/l	113.3 - 233.3	97.9 - 346.	4 65.7 - 451.8	61.8 - 430.5
Sodium	mmol/l	142.2 - 146.3	148.3 - 152.3	143.1 - 147.6	139.3 - 145.3
Potassium	mmol/l	3.35 - 3.92	3.44 - 4.67	3.76 - 4.31	2.6 - 4.6
Chloride	mmol/l	100.5 - 104.5	109.5 - 118.7	104.8 - 109.5	91.5 - 106.7
Calcium	mmol/l	2.49 - 2.64	2.62 - 2.81	2.58 - 2.77	2.54 - 2.92
Phosphorus	mmol/l	1.82 - 2.50	1.27 - 1.86	1.12 - 1.89	0.9 - 2.03
Protein	g/l	63.12 - 69.96	68.52 - 78.52	68.58 - 84.03	64.14 - 83.74
Albumin	g/l	41.79 - 44.69	30.83 - 49.48	43.23 - 54.01	33.83 - 52.45

Hsd:Sprague Dawley® SD®

STUDY C11963 | ORGAN WEIGHTS

GROUP 1 MALES - FEED	28 DAYS ∩ = 20	13 WEEKS ∩ = 20	26 WEEKS ∩ = 20	104 WEEKS ∩ = 20
Adrenal	0.05 + 0.01	0.06 + 0.01	0.06 + 0.01	0.11 + 0.10
Brain	1.84 + 0.06	1.94 + 0.05	1.97 + 0.07	2.10 + 0.06
Epididymis	1.10 + 0.08	1.35 + 0.10	1.35 + 0.17	1.29 + 0.18
Heart	1.19 + 0.09	1.39 + 0.10	1.51 + 0.12	2.13 + 0.22
Kidneys	2.17 + 0.20	2.91 + 2.24	2.59 + 0.29	3.97 + 0.72
Liver	11.0 + 1.02	12.1 + 1.24	13.9 + 1.73	20.1 + 5.52
Spleen	0.92 + .11	0.96 + 0.11	0.991 + 0.14	1.51 + 0.31
Testicular	3.66 + 0.2	3.95 + 0.24	3.96 + 0.78	4.23 + 0.78
Thymus	0.50 + 0.1	0.31 + 0.04	0.192 + 0.06	0.13 + 0.03

GROUP 2 MALES - GAVAGE	28 DAYS ∩ = 20	13 WEEKS ∩ = 20	26 WEEKS ∩ = 20	104 WEEKS ∩ = 20
Adrenal	0.05 + 0.01	0.06 + 0.01	0.05 + 0.01	0.09 + 0.08
Brain	1.85 + 0.05	1.94 + 0.05	2.10 + 0.06	2.07 + 0.07
Epididymis	1.10 + 0.09	1.35 + 0.12	1.29 + 0.18	1.22 + 0.18
Heart	1.18 + 0.08	1.37 + 0.12	2.13 + 0.22	2.15 + 0.27
Kidneys	2.05 + 0.16	2.38 + 0.23	2.54 + 0.24	3.89 + 0.63
Liver	9.52 + 0.71	12.3 + 1.46	13.1 + 1.26	18.58 + 2.64
Spleen	0.85 + 0.08	0.98 + 0.15	0.96 + 0.11	1.53 + 0.29
Testicular	3.66 + 0.16	3.98 + 0.36	4.16 + 0.22	3.82 + 1.01
Thymus	0.50 + 0.10	0.29 + 0.04	0.20 + 0.06	0.16 + 0.14

*Data represents average organ weight (g) ± one standard deviation

Hsd:Sprague Dawley® SD®

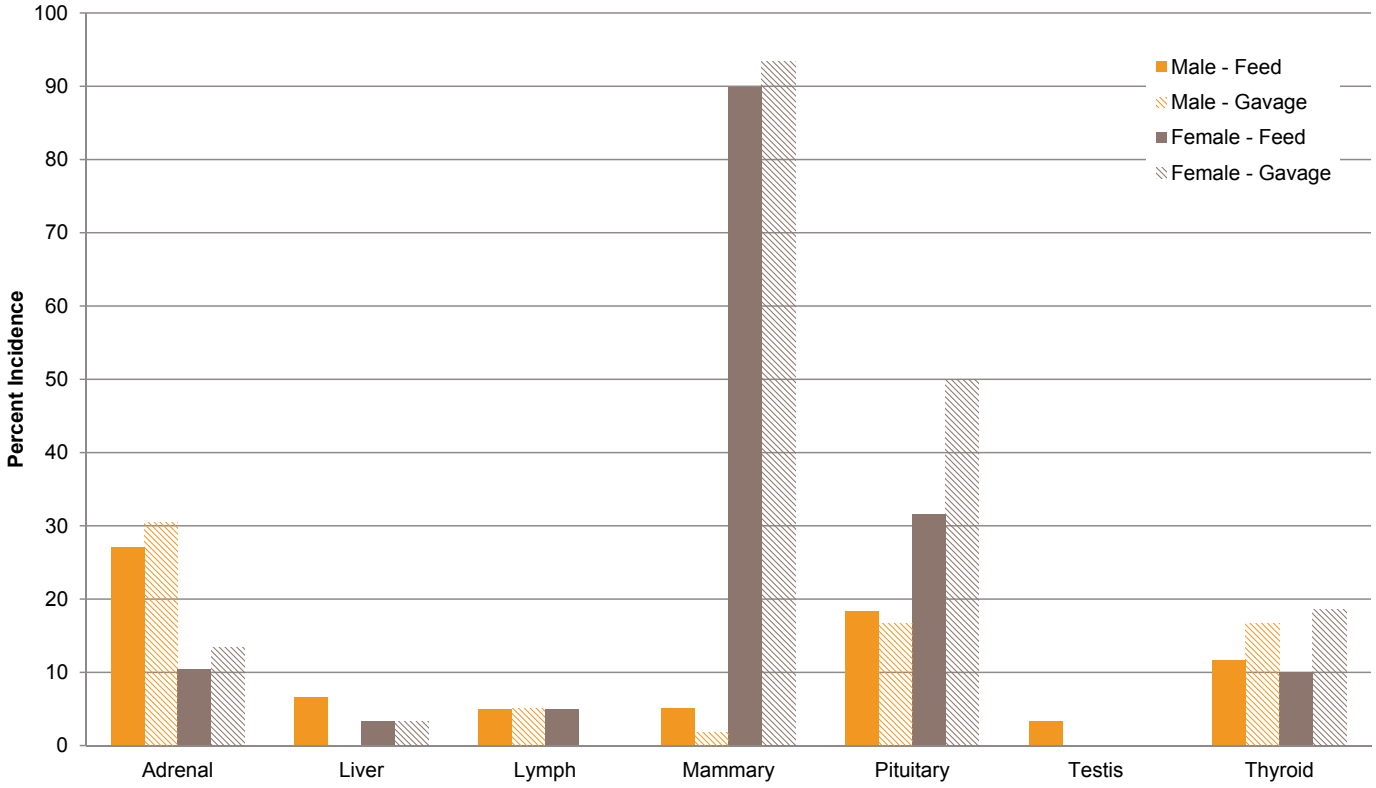
STUDY C11963 | ORGAN WEIGHTS

GROUP 1 FEMALES - FEED	28 DAYS n = 20	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 29
Adrenal	0.07 + 0.01	0.06 + 0.01	0.06 + 0.01	0.06 + 0.01
Brain	1.72 + 0.05	1.78 + 0.05	1.83 + 0.09	1.84 + 0.06
Heart	0.87 + 0.07	0.95 + 0.05	0.99 + 0.08	1.40 + 0.19
Kidneys	1.37 + 0.12	1.44 + 0.10	1.51 + 0.13	2.04 + 0.23
Liver	6.50 + 0.68	6.55 + 0.68	6.90 + 0.93	11.7 + 3.30
Ovaries	0.11 + 0.02	0.10 + 0.01	0.10 + 0.03	0.22 + 0.70
Spleen	0.67 + 0.09	0.66 + 0.09	0.69 + 0.12	0.95 + 0.30
Thymus	0.37 + 0.06	0.24 + 0.03	0.17 + 0.03	0.09 + 0.03

GROUP 2 FEMALES - GAVAGE	28 DAYS n = 20	13 WEEKS n = 20	26 WEEKS n = 20	104 WEEKS n = 28
Adrenal	0.07 + 0.01	0.07 + 0.01	0.06 + 0.004	0.06 + 0.25
Brain	1.72 + 0.04	1.80 + 0.05	1.80 + 0.05	1.83 + 0.06
Heart	0.85 + 0.06	0.98 + 0.07	0.10 + 0.08	1.37 + 0.14
Kidneys	1.37 + 0.12	1.50 + 0.12	1.50 + 0.12	2.18 + 0.34
Liver	6.70 + 0.70	6.91 + 0.91	6.72 + 0.61	12.0 + 3.00
Ovaries	0.10 + 0.02	0.10 + 0.02	0.10 + 0.20	0.16 + 0.25
Spleen	0.65 + 0.08	0.71 + 0.10	0.66 + 0.10	0.98 + 0.35
Thymus	0.37 + 0.06	0.26 + 0.05	0.17 + 0.04	0.09 + 0.02

*Data represents average organ weight (g) ± one standard deviation

Hsd:Sprague Dawley® SD® Spontaneous Tumor Incidence



Age at study start: Approximately 11 weeks
Maintained on Kliba Nafag 3433
Study C11963

PATHOLOGY REPORT PAGE : 53/2035
SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
HEART :	-	-	-	-	-	-	60	60
- Endocardial schwann.:	-	-	-	-	-	-	-	1
LUNG :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
PHARYNX :	-	-	-	-	-	-	60	60
- Squamous papilloma :	-	-	-	-	-	-	-	1
STOMACH :	-	-	-	-	-	-	60	60
- Papilloma, forestom.:	-	-	-	-	-	-	-	1
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
JEJUNUM :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	-	1
CECUM :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
COLON :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
RECTUM :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	-	1
LIVER :	-	-	-	-	-	-	60	60
- Adenoma hepatocell. :	-	-	-	-	-	-	1	-
- Cholangioma :	-	-	-	-	-	-	1	1
- Metastatic carcinoma:	-	-	-	-	-	-	-	1
PANCREAS :	-	-	-	-	-	-	60	60
- Islets cell adenoma :	-	-	-	-	-	-	2	1
- Islet cell carcinoma:	-	-	-	-	-	-	3	-
- Exocrine carcinoma :	-	-	-	-	-	-	1	-
- Metastatic carcinoma:	-	-	-	-	-	-	1	1

PATHOLOGY REPORT PAGE : 54/2035
SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.* : 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
KIDNEYS :	-	-	-	-	-	-	60	60
- Metastatic cacinoma :	-	-	-	-	-	-	-	1
URETERS :	-	-	-	-	-	-	59	59
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
OVARIES :	-	-	-	-	-	-	60	60
- Sertoli cell tumor :	-	-	-	-	-	-	-	1
- Granulosa tumor, m. :	-	-	-	-	-	-	1	-
- Metastatic carcinoma:	-	-	-	-	-	-	1	2
UTERUS :	-	-	-	-	-	-	60	60
- Endometrial polyp :	-	-	-	-	-	-	1	1
- Stromal polyp :	-	-	-	-	-	-	3	5
- Adenoma :	-	-	-	-	-	-	-	2
- Leimyosarcoma :	-	-	-	-	-	-	1	-
- Adenocarcinoma :	-	-	-	-	-	-	1	2
- Stromal sarcoma :	-	-	-	-	-	-	-	1
- Malignant schwannoma:	-	-	-	-	-	-	1	-
- Metastatic carcinoma:	-	-	-	-	-	-	-	1
CERVIX :	-	-	-	-	-	-	60	60
- Squamous carcinoma :	-	-	-	-	-	-	-	1
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
- Metastatic sarcoma :	-	-	-	-	-	-	-	1
VAGINA :	-	-	-	-	-	-	60	60
- Granular cell tumor :	-	-	-	-	-	-	1	-
- Metastatic sarcoma :	-	-	-	-	-	-	-	1
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
CLITORAL GLANDS :	-	-	-	-	-	-	2	-
- Squamous carcinoma :	-	-	-	-	-	-	1	-
PITUITARY GLAND :	-	-	-	-	-	-	60	60
- Adenoma: p.anterior :	-	-	-	-	-	-	19	29
- Adenoma:p.intermedia:	-	-	-	-	-	-	-	1

PATHOLOGY REPORT PAGE : 55/2035
SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
THYROID GLAND :	-	-	-	-	-	-	60	59
- C-cell adenoma :	-	-	-	-	-	-	5	10
- C-cell carcinoma :	-	-	-	-	-	-	-	1
- Follicular carcinoma:	-	-	-	-	-	-	1	-
PARATHYROID GLANDS :	-	-	-	-	-	-	51	51
- Adenoma :	-	-	-	-	-	-	-	1
ADRENAL CORTICES :	-	-	-	-	-	-	58	60
- Adenoma :	-	-	-	-	-	-	3	6
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
ADRENAL MEDULLAS :	-	-	-	-	-	-	57	59
- Pheochromocytoma b. :	-	-	-	-	-	-	2	1
- Complex pheochr. m. :	-	-	-	-	-	-	-	1
HEMOLYMPHORET. SYS. :	-	-	-	-	-	-	60	60
- Histiocytic sarcoma :	-	-	-	-	-	-	1	-
- Malignant lymphoma :	-	-	-	-	-	-	2	-
SPLEEN :	-	-	-	-	-	-	60	60
- Metastatic carcinoma:	-	-	-	-	-	-	1	1
THYMUS :	-	-	-	-	-	-	57	58
- Thymoma, epith.,ben.:	-	-	-	-	-	-	1	-
- Thymoma, lymph.,ben.:	-	-	-	-	-	-	1	-
MESENT. LYMPH NODE :	-	-	-	-	-	-	59	60
- Hemangiosarcoma :	-	-	-	-	-	-	1	-
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
MANDIBULAR GLANDS :	-	-	-	-	-	-	60	59
- Adenoma :	-	-	-	-	-	-	1	-

PATHOLOGY REPORT
SUMMARY TABLES

TEST ITEM : Control Data
TEST SYSTEM : RAT, 104-Week, Internal Test
SPONSOR : Harlan Laboratories

PATHOL. NO. : 41968 WEK
DATE : 11-OCT-12
PathData©System V6.2d2

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	–	–	–	–	–	–	60	60
MAMMARY GLAND :	–	–	–	–	–	–	59	60
– Adenoma :	–	–	–	–	–	–	–	1
– Fibroadenoma :	–	–	–	–	–	–	44	43
– Carc.in fibroadenoma:	–	–	–	–	–	–	2	2
– Adenocarcinoma :	–	–	–	–	–	–	7	9
– Adenoacanthoma :	–	–	–	–	–	–	–	1
SKIN/SUBCUTIS :	–	–	–	–	–	–	60	60
– Papilloma :	–	–	–	–	–	–	–	1
– Fibroma :	–	–	–	–	–	–	3	–
– Sebaceous adenoma :	–	–	–	–	–	–	1	–
– Keratoacanthoma :	–	–	–	–	–	–	1	–

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TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104—Week, Internal Test *DATE* : 11—OCT—12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON—NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	—	—	—	—	—	—	60	60
GENERAL OBSERVATIONS :	—	—	—	—	—	—	5	3
— Observation confirm.:	—	—	—	—	—	—	5	3
CEREBRUM :	—	—	—	—	—	—	60	60
— No histol.correlate :	—	—	—	—	—	—	—	1
— Area of compression :	—	—	—	—	—	—	8	13
CEREBELLUM :	—	—	—	—	—	—	60	60
— Hemorrhage :	—	—	—	—	—	—	1	—
MEDULLA OBLONGATA :	—	—	—	—	—	—	60	60
— Nerve fiber degen. :	—	—	—	—	—	—	10	14
SPINAL CORD, CERVIC. :	—	—	—	—	—	—	59	60
— Hemorrhage :	—	—	—	—	—	—	1	—
— Radiculoneuropathy :	—	—	—	—	—	—	1	—
SPINAL CORD, THORAC. :	—	—	—	—	—	—	59	60
— Radiculoneuropathy :	—	—	—	—	—	—	4	6
SPINAL CORD, LUMBAR :	—	—	—	—	—	—	59	60
— Radiculoneuropathy :	—	—	—	—	—	—	23	22
SCIATIC NERVES :	—	—	—	—	—	—	60	60
— Nerve fiber degen. :	—	—	—	—	—	—	50	54
HEART :	—	—	—	—	—	—	60	60
— Mononuclear foci :	—	—	—	—	—	—	2	3
— Myocardial necrosis :	—	—	—	—	—	—	—	1
— Chr.prog.cardiomyop.:	—	—	—	—	—	—	20	26
NASOPHARYNGEAL DUCT :	—	—	—	—	—	—	60	60
— Hemorrhage :	—	—	—	—	—	—	1	—
— Secretion :	—	—	—	—	—	—	1	—

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
NASAL CAV.,LEVEL 1 :	-	-	-	-	-	-	60	60
- Hyaline inclusions :	-	-	-	-	-	-	10	9
- Inflammatory secret.:	-	-	-	-	-	-	-	2
- Inflammation:submuc.:	-	-	-	-	-	-	2	-
- Epithelial degen. :	-	-	-	-	-	-	1	-
- Sero-mucinous secr. :	-	-	-	-	-	-	-	1
NASAL CAV.,LEVEL 2 :	-	-	-	-	-	-	60	60
- Food in lumen :	-	-	-	-	-	-	1	-
- Hyaline inclusions :	-	-	-	-	-	-	38	30
- Respiratory hyperpl.:	-	-	-	-	-	-	-	1
- Sero-mucinous secr. :	-	-	-	-	-	-	-	1
- Inflammatory secret.:	-	-	-	-	-	-	1	1
- Inflammation, submu.:	-	-	-	-	-	-	2	-
- Epithelial degen. :	-	-	-	-	-	-	1	1
NASAL CAV.,LEVEL 3 :	-	-	-	-	-	-	60	60
- Sero-mucinous secr. :	-	-	-	-	-	-	-	1
- Inflammatory secret.:	-	-	-	-	-	-	1	-
- Hyaline inclusions :	-	-	-	-	-	-	41	40
- Submucosal inflamm. :	-	-	-	-	-	-	1	2
- Epithelial degener. :	-	-	-	-	-	-	1	1
NASAL CAV.,LEVEL 4 :	-	-	-	-	-	-	60	60
- Hyaline inclusions :	-	-	-	-	-	-	30	51
- Sero-mucinous secr. :	-	-	-	-	-	-	-	1
- Inflammatory secret.:	-	-	-	-	-	-	1	-
- Inflammation, subm. :	-	-	-	-	-	-	1	-
- Epithelial degener. :	-	-	-	-	-	-	1	1
LARYNX :	-	-	-	-	-	-	60	60
- Food in lumen :	-	-	-	-	-	-	2	3
- Dissecated secretion:	-	-	-	-	-	-	1	1
- Inflammation :	-	-	-	-	-	-	3	3
- Glandular inflamm. :	-	-	-	-	-	-	1	-

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TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
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SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
TRACHEA :	-	-	-	-	-	-	60	60
- Glandular dilation :	-	-	-	-	-	-	7	3
LUNG :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	8	3
- Foreign mat./food p.:	-	-	-	-	-	-	4	8
- Osseous metaplasia :	-	-	-	-	-	-	3	1
- Vascular mineraliz. :	-	-	-	-	-	-	48	44
- Congestion :	-	-	-	-	-	-	3	4
- Alveolar edema :	-	-	-	-	-	-	-	1
- Alveolar macrophages:	-	-	-	-	-	-	17	10
- Alveolitis :	-	-	-	-	-	-	1	-
- Granuloma(s) :	-	-	-	-	-	-	2	-
- Inflammation, inter.:	-	-	-	-	-	-	4	3
- Inflammation: bron. :	-	-	-	-	-	-	2	3
- Hyperpl., alv./bron.:	-	-	-	-	-	-	1	-
TONGUE :	-	-	-	-	-	-	60	59
- Atrophy, saliv.gl. :	-	-	-	-	-	-	-	1
- Vacuolar deg.sal.gl.:	-	-	-	-	-	-	2	-
TOOTH/TEETH :	-	-	-	-	-	-	60	60
- Dental dysplasia :	-	-	-	-	-	-	-	1
- Root inflammation :	-	-	-	-	-	-	-	1
- Abscess :	-	-	-	-	-	-	1	-
ESOPHAGUS :	-	-	-	-	-	-	60	59
- No histological cor.:	-	-	-	-	-	-	2	2
- Food in lumen :	-	-	-	-	-	-	3	-
- Dilation :	-	-	-	-	-	-	2	1
- Diverticulum :	-	-	-	-	-	-	-	1

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
STOMACH :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	3	1
- Glandular dilation :	-	-	-	-	-	-	31	34
- Congestion :	-	-	-	-	-	-	1	1
- Lymphoid follicles :	-	-	-	-	-	-	3	3
- Mononuclear foci :	-	-	-	-	-	-	1	-
- Erosion(s) gland. :	-	-	-	-	-	-	2	1
- Squamous hyperplasia:	-	-	-	-	-	-	3	-
- Hyperkeratosis :	-	-	-	-	-	-	2	-
DUODENUM :	-	-	-	-	-	-	60	60
- Glandular dilation :	-	-	-	-	-	-	1	-
ILEUM :	-	-	-	-	-	-	60	60
- Dilation :	-	-	-	-	-	-	-	1
PEYER'S P.-JEJUNUM :	-	-	-	-	-	-	59	60
- Observation confirm.:	-	-	-	-	-	-	1	-
- Mineralization :	-	-	-	-	-	-	1	-
PEYER'S P.-ILEUM :	-	-	-	-	-	-	52	55
- Observation confirm.:	-	-	-	-	-	-	1	-
CECUM :	-	-	-	-	-	-	60	60
- No histol.correlate :	-	-	-	-	-	-	1	-
RECTUM :	-	-	-	-	-	-	60	60
- Nematodes :	-	-	-	-	-	-	1	3
- Ulceration :	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
LIVER :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	5	4
- Misshapen :	-	-	-	-	-	-	2	1
- Hepatodiaphrag.nod. :	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	1	-
- Peliosis hepatis :	-	-	-	-	-	-	2	-
- Hemosiderin :	-	-	-	-	-	-	4	6
- Kupffer's cell pigm.:	-	-	-	-	-	-	-	1
- Mineralization :	-	-	-	-	-	-	1	-
- Erythropoiesis :	-	-	-	-	-	-	17	19
- Granulopoiesis :	-	-	-	-	-	-	2	-
- Hepatocel.hypertr. :	-	-	-	-	-	-	6	4
- Inflammatory foci :	-	-	-	-	-	-	10	6
- Focal fibrosis :	-	-	-	-	-	-	1	-
- Peribiliary fibrosis:	-	-	-	-	-	-	2	2
- Peribiliar inflamm. :	-	-	-	-	-	-	2	1
- Bile duct prolifer. :	-	-	-	-	-	-	8	8
- Biliary cysts :	-	-	-	-	-	-	3	3
- Fatty change :	-	-	-	-	-	-	22	22
- Vacuolated foci :	-	-	-	-	-	-	6	2
- Hepatocel.degener. :	-	-	-	-	-	-	3	1
- Peritonitis :	-	-	-	-	-	-	-	1
- Hemorrhagic necrosis:	-	-	-	-	-	-	-	1
- Clear cell foci :	-	-	-	-	-	-	17	9
- Basophilic foci :	-	-	-	-	-	-	5	1
- Eosinophilic foci :	-	-	-	-	-	-	1	-
- Mixed foci :	-	-	-	-	-	-	1	1
PANCREAS :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Congestion :	-	-	-	-	-	-	3	-
- Edema, interstitial :	-	-	-	-	-	-	1	1
- Hemosiderin: islets :	-	-	-	-	-	-	-	1
- Vacuolation :	-	-	-	-	-	-	-	1
- Exocrine atrophy :	-	-	-	-	-	-	4	3
- Inflammation :	-	-	-	-	-	-	-	2
- Islet cell hyperpl. :	-	-	-	-	-	-	-	4

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SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
KIDNEYS :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Tubular cyst(s) :	-	-	-	-	-	-	1	-
- Pelvic dilation :	-	-	-	-	-	-	3	1
- Hydronephrosis :	-	-	-	-	-	-	1	-
- Hemosiderin :	-	-	-	-	-	-	7	7
- Hyaline droplets :	-	-	-	-	-	-	1	-
- Cortical mineraliz. :	-	-	-	-	-	-	5	6
- Medullar mineraliz. :	-	-	-	-	-	-	7	13
- Pelvic mineraliz. :	-	-	-	-	-	-	26	34
- Papillary mineraliz.:	-	-	-	-	-	-	2	-
- Tubular dilation :	-	-	-	-	-	-	4	1
- Tubular basophilia :	-	-	-	-	-	-	25	21
- Tubular casts :	-	-	-	-	-	-	29	31
- Tubular vacuolation :	-	-	-	-	-	-	2	-
- Interstit. fibrosis :	-	-	-	-	-	-	-	1
- Mononuclear foci :	-	-	-	-	-	-	4	3
- Scaring (infarct) :	-	-	-	-	-	-	1	2
- Pyelitis :	-	-	-	-	-	-	3	3
- Inflammation inters.:	-	-	-	-	-	-	1	-
- Peritonitis :	-	-	-	-	-	-	1	-
- Chronic nephropathy :	-	-	-	-	-	-	16	18
- Telangiectasis :	-	-	-	-	-	-	1	3
- Lymphangieactsis :	-	-	-	-	-	-	1	-
- Renal atrophy :	-	-	-	-	-	-	-	1
- Urothelial hyperpl. :	-	-	-	-	-	-	11	19
- Tubular proliferat. :	-	-	-	-	-	-	1	1
- Focal tub.hyperp. :	-	-	-	-	-	-	1	-
URETERS :	-	-	-	-	-	-	59	59
- Dilation :	-	-	-	-	-	-	2	1
- Peritonitis :	-	-	-	-	-	-	-	1

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
URINARY BLADDER :	-	-	-	-	-	-	57	60
- Distension :	-	-	-	-	-	-	1	-
- Mineralization :	-	-	-	-	-	-	-	1
- Mononuclear foci :	-	-	-	-	-	-	1	6
- Serosal inflammation:	-	-	-	-	-	-	-	2
- Urothelial hyperpl. :	-	-	-	-	-	-	-	1
OVARIES :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	3	3
- Luteal cyst :	-	-	-	-	-	-	11	9
- Rete cyst :	-	-	-	-	-	-	1	-
- Follicular cyst :	-	-	-	-	-	-	-	1
- Epithelial cyst :	-	-	-	-	-	-	2	5
- Bursa dilation :	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	5	1
- Hyperpl./troph.c.lut:	-	-	-	-	-	-	-	2
- Senile atrophy :	-	-	-	-	-	-	58	55
- Peritonitis :	-	-	-	-	-	-	-	1
- Inflammation :	-	-	-	-	-	-	1	-
- Interstitial hyper. :	-	-	-	-	-	-	1	-
- Sertoli cell hyper. :	-	-	-	-	-	-	7	9
- Granulosa cell hyp. :	-	-	-	-	-	-	15	13
UTERUS :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Gartner-cyst :	-	-	-	-	-	-	-	1
- Hydrometra :	-	-	-	-	-	-	-	2
- Myxometra :	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	13	7
- Endometrial cyst(s) :	-	-	-	-	-	-	2	9
- Endometritis :	-	-	-	-	-	-	-	1
- Atrophy :	-	-	-	-	-	-	1	-
- Cystic hyperplasia :	-	-	-	-	-	-	8	5
- Squamous metaplasia :	-	-	-	-	-	-	2	1
- Endometrial fibrosis:	-	-	-	-	-	-	-	1
- Squam.metapl./hyper.:	-	-	-	-	-	-	8	26
- Hyperkeratosis :	-	-	-	-	-	-	4	13

09009e5380bf41d2

1530

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
CERVIX :	-	-	-	-	-	-	60	60
- Cervical hypertrophy:	-	-	-	-	-	-	1	2
- Cervical atrophy :	-	-	-	-	-	-	1	-
- Squam.metapl./hyper.:	-	-	-	-	-	-	16	29
- Hyperkeratosis :	-	-	-	-	-	-	11	26
- Mucification :	-	-	-	-	-	-	-	1
VAGINA :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Cellular detritus :	-	-	-	-	-	-	1	-
- Anestrus :	-	-	-	-	-	-	16	5
- Proestrus :	-	-	-	-	-	-	4	1
- Estrus :	-	-	-	-	-	-	2	-
- Metestrus :	-	-	-	-	-	-	2	4
- Diestrus :	-	-	-	-	-	-	9	16
- Inflammation :	-	-	-	-	-	-	1	-
- Mucification :	-	-	-	-	-	-	12	13
PITUITARY GLAND :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	2	1
- Stomatodeal remnants:	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	2	-
- Cyst(s):p.anterior :	-	-	-	-	-	-	3	-
- Cyst(s):p.intermedia:	-	-	-	-	-	-	4	-
- Cystic Rathke's cl. :	-	-	-	-	-	-	-	4
- Hemosiderin :	-	-	-	-	-	-	1	-
- Fatty change, focal :	-	-	-	-	-	-	1	-
- Angiectasis :	-	-	-	-	-	-	3	-
- Hyperpl.p.ant.focal :	-	-	-	-	-	-	3	7
- Hyperplasia, diffuse:	-	-	-	-	-	-	2	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
THYROID GLAND :	-	-	-	-	-	-	60	59
- No histological cor.:	-	-	-	-	-	-	-	1
- Congestion :	-	-	-	-	-	-	1	1
- Ductal remnants :	-	-	-	-	-	-	7	8
- Follicular dilation :	-	-	-	-	-	-	2	-
- C-cell hyperpl.focal:	-	-	-	-	-	-	9	10
- C-cell hyperpl.diff.:	-	-	-	-	-	-	2	4
- Foll.hyperpl.focal :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	-	1
PARATHYROID GLANDS :	-	-	-	-	-	-	51	51
- Hyperplasia focal :	-	-	-	-	-	-	2	-
ADRENAL CORTICES :	-	-	-	-	-	-	58	60
- No histological cor.:	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	1	3
- Extra-adrenal tissue:	-	-	-	-	-	-	5	10
- Fatty change:diffuse:	-	-	-	-	-	-	1	1
- Fatty change:focal :	-	-	-	-	-	-	8	4
- Cystic degeneration :	-	-	-	-	-	-	7	14
- Angiectasis :	-	-	-	-	-	-	11	11
- Thrombosis :	-	-	-	-	-	-	2	2
- Peritonitis :	-	-	-	-	-	-	-	1
- Atrophy :	-	-	-	-	-	-	6	3
- Diffuse hypertrophy :	-	-	-	-	-	-	1	-
- Hypertr.focal:glom. :	-	-	-	-	-	-	47	49
- Hypertr.focal:fasc. :	-	-	-	-	-	-	4	1
- Focal hyperplasia :	-	-	-	-	-	-	17	12
ADRENAL MEDULLAS :	-	-	-	-	-	-	57	59
- Hyperplasia focal :	-	-	-	-	-	-	2	-

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TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
SPLEEN :	-	-	-	-	-	-	60	60
- Accessory spleen :	-	-	-	-	-	-	-	4
- Erythropoiesis :	-	-	-	-	-	-	56	56
- Granulopoiesis :	-	-	-	-	-	-	6	1
- Hemosiderin :	-	-	-	-	-	-	55	60
- Lymphoid atrophy :	-	-	-	-	-	-	11	14
- Inflammation :	-	-	-	-	-	-	1	-
- Peritonitis :	-	-	-	-	-	-	-	1
BONE MARROW-FEMORAL :	-	-	-	-	-	-	60	60
- Increased erythrop. :	-	-	-	-	-	-	3	5
- Increased granulopo.:	-	-	-	-	-	-	15	11
- Hypocellularity :	-	-	-	-	-	-	32	38
BONE MARROW-STERNAL :	-	-	-	-	-	-	60	60
- Increased erythrop. :	-	-	-	-	-	-	2	3
- Increased granulopo.:	-	-	-	-	-	-	12	7
- Hypocellularity :	-	-	-	-	-	-	36	30
- Panmyelophthisis :	-	-	-	-	-	-	-	1
- Angiectasis :	-	-	-	-	-	-	1	1
THYMUS :	-	-	-	-	-	-	57	58
- Food part., mediast.:	-	-	-	-	-	-	-	1
- Congestion/hemorrh. :	-	-	-	-	-	-	4	4
- Cyst(s) :	-	-	-	-	-	-	23	35
- Hemosiderin :	-	-	-	-	-	-	1	-
- Involution/Atrophy :	-	-	-	-	-	-	54	58
- Epithelial hyperpl. :	-	-	-	-	-	-	19	28
LYMPH NODES :	-	-	-	-	-	-	4	-
- Congestion :	-	-	-	-	-	-	1	-
- Hemosiderin :	-	-	-	-	-	-	1	-
- Plasma cells :	-	-	-	-	-	-	2	-
- Sinusoidal dilation :	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
MESENT. LYMPH NODE :	-	-	-	-	-	-	59	60
- Congestion :	-	-	-	-	-	-	1	-
- Hemosiderin :	-	-	-	-	-	-	2	5
- Pigment-laden hist. :	-	-	-	-	-	-	54	57
- Plasma cells :	-	-	-	-	-	-	1	1
- Histiocytosis :	-	-	-	-	-	-	-	1
- Lymphoid hyperplasia:	-	-	-	-	-	-	-	2
- Lymphoid atrophy :	-	-	-	-	-	-	4	1
- Stromal cell hyperp.:	-	-	-	-	-	-	1	-
POPLITEAL LNN. :	-	-	-	-	-	-	58	58
- No histological cor.:	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	2	1
- Hemosiderin :	-	-	-	-	-	-	5	9
- Activation :	-	-	-	-	-	-	-	2
- Plasma cells :	-	-	-	-	-	-	7	2
- Lymphoid atrophy :	-	-	-	-	-	-	1	1
MANDIB.LYMPH NODES :	-	-	-	-	-	-	60	59
- Congestion :	-	-	-	-	-	-	7	2
- Hemosiderin :	-	-	-	-	-	-	4	7
- Plasma cells :	-	-	-	-	-	-	46	44
- Activation :	-	-	-	-	-	-	1	-
- Lymphoid atrophy :	-	-	-	-	-	-	1	-
- Sinusoidal dilation :	-	-	-	-	-	-	2	2
SUBLINGUAL GLANDS :	-	-	-	-	-	-	60	59
- Acinar atrophy :	-	-	-	-	-	-	1	-
- Ductal dilation :	-	-	-	-	-	-	1	-
MANDIBULAR GLANDS :	-	-	-	-	-	-	60	59
- Dilated ducts :	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
HARDERIAN GLANDS :	-	-	-	-	-	-	60	60
- Hemorrhage :	-	-	-	-	-	-	4	2
- Porphyrin deposition:	-	-	-	-	-	-	58	57
- Acinar dilation :	-	-	-	-	-	-	8	6
- Glandular atrophy :	-	-	-	-	-	-	1	1
- Mononuclear foci :	-	-	-	-	-	-	3	4
- Inflammation :	-	-	-	-	-	-	4	4
EXORBITAL LACR.GLDS. :	-	-	-	-	-	-	60	60
- Hemorrhage :	-	-	-	-	-	-	-	1
- Porphyrin deposition:	-	-	-	-	-	-	-	1
- Harderian alteration:	-	-	-	-	-	-	13	11
- Increased vacuolat. :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	1	1
MAMMARY GLAND :	-	-	-	-	-	-	59	60
- Secretion :	-	-	-	-	-	-	25	37
- Dilated ducts :	-	-	-	-	-	-	17	24
- Galactocele :	-	-	-	-	-	-	1	4
- Ceroid pigment :	-	-	-	-	-	-	1	-
- Mineralization :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	1	1
- Abscess :	-	-	-	-	-	-	-	1
- Glandular hyperpl. :	-	-	-	-	-	-	22	18
SKIN/SUBCUTIS :	-	-	-	-	-	-	60	60
- Adnexal atrophy :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	1	-
- Intradermal fibrosis:	-	-	-	-	-	-	2	-
- Subcutaneous fibros.:	-	-	-	-	-	-	1	-
SKELETAL MUSCLE :	-	-	-	-	-	-	60	59
- Myofiber degener. :	-	-	-	-	-	-	-	1
BONE :	-	-	-	-	-	-	2	-
- No histological cor.:	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								FEMALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
EYES :	-	-	-	-	-	-	59	59
- Hemorrhage :	-	-	-	-	-	-	11	10
- Lenticular degener. :	-	-	-	-	-	-	1	1
- Inflammation orbit. :	-	-	-	-	-	-	7	5
- Corneal hyperplasia :	-	-	-	-	-	-	1	-
- Corneal hyperkerat. :	-	-	-	-	-	-	2	-
- Corneal epith.thin. :	-	-	-	-	-	-	1	-
- Keratitis :	-	-	-	-	-	-	1	-
- Phtisis bulbi :	-	-	-	-	-	-	1	1
INNER EARS :	-	-	-	-	-	-	4	2
- Abscess :	-	-	-	-	-	-	4	2
BODY CAVITIES :	-	-	-	-	-	-	4	3
- No histological cor.:	-	-	-	-	-	-	1	-
- Fat necrosis :	-	-	-	-	-	-	1	2
CAUSE DEATH/MORBID. :	-	-	-	-	-	-	31	32
- Accidental :	-	-	-	-	-	-	-	1
- Inflammation/Necros.:	-	-	-	-	-	-	2	-
- Systemic neoplasia :	-	-	-	-	-	-	2	-
- Pituitary neoplasm :	-	-	-	-	-	-	3	5
- Mammary gland neopl.:	-	-	-	-	-	-	21	23
- Other tumors :	-	-	-	-	-	-	4	2
- Unknown :	-	-	-	-	-	-	1	1
STERNUM :	-	-	-	-	-	-	60	60
- Chondromuc.degener. :	-	-	-	-	-	-	15	12
- Fibrous osteodystr. :	-	-	-	-	-	-	2	-

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TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
CEREBRUM :	-	-	-	-	-	-	60	60
- Pinealoma :	-	-	-	-	-	-	1	-
- Metastatic carcinoma:	-	-	-	-	-	-	1	-
HEART :	-	-	-	-	-	-	60	60
- Endocardial schwann.:	-	-	-	-	-	-	1	1
- Parganglioma :	-	-	-	-	-	-	-	1
NASOPHARYNGEAL DUCT :	-	-	-	-	-	-	60	60
- Metastatic sarcoma :	-	-	-	-	-	-	1	-
LUNG :	-	-	-	-	-	-	60	60
- Carcinoma, alv./bron:	-	-	-	-	-	-	-	1
ORAL CAVITY :	-	-	-	-	-	-	-	1
- Squamous carcinoma :	-	-	-	-	-	-	-	1
TOOTH/TEETH :	-	-	-	-	-	-	60	60
- Squam.carcinom, ging:	-	-	-	-	-	-	-	1
JEJUNUM :	-	-	-	-	-	-	60	59
- Adenocarcinoma :	-	-	-	-	-	-	1	-
LIVER :	-	-	-	-	-	-	60	60
- Adenoma hepatocell. :	-	-	-	-	-	-	1	-
- Carcinoma hepatocel.:	-	-	-	-	-	-	1	-
- Cholangiocarcinoma :	-	-	-	-	-	-	2	-
PANCREAS :	-	-	-	-	-	-	58	60
- Islets cell adenoma :	-	-	-	-	-	-	6	3
- Islet cell carcinoma:	-	-	-	-	-	-	2	1
- Exocrine adenoma :	-	-	-	-	-	-	2	2
URETERS :	-	-	-	-	-	-	60	59
- Urothelial papilloma:	-	-	-	-	-	-	-	1

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SUMMARY TABLES

TEST ITEM : Control Data
TEST SYSTEM : RAT, 104-Week, Internal Test
SPONSOR : Harlan Laboratories

PATHOL. NO.: 41968 WEK
DATE : 11-OCT-12
PathData©System V6.2d2

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	–	–	–	–	–	–	60	60
URINARY BLADDER :	–	–	–	–	–	–	60	60
– Urothelial papilloma:	–	–	–	–	–	–	–	1
TESTES :	–	–	–	–	–	–	59	60
– Leydig cell tumor :	–	–	–	–	–	–	1	–
– Metastatic mesothel.:	–	–	–	–	–	–	1	–
EPIDIDYMIDES :	–	–	–	–	–	–	59	60
– Metastatic mesothel.:	–	–	–	–	–	–	1	–
– Metastatic sarcoma :	–	–	–	–	–	–	1	–
PREPUTIAL GLANDS :	–	–	–	–	–	–	2	2
– Squamous carcinoma :	–	–	–	–	–	–	–	1
PITUITARY GLAND :	–	–	–	–	–	–	60	60
– Adenoma: p.anterior :	–	–	–	–	–	–	11	9
– Adenoma:p.intermedia:	–	–	–	–	–	–	–	1
THYROID GLAND :	–	–	–	–	–	–	60	60
– C-cell adenoma :	–	–	–	–	–	–	6	7
– C-cell carcinoma :	–	–	–	–	–	–	–	3
– Follicular carcinoma:	–	–	–	–	–	–	1	–
PARATHYROID GLANDS :	–	–	–	–	–	–	53	56
– Adenoma :	–	–	–	–	–	–	6	6
– Metastatic carcinoma:	–	–	–	–	–	–	–	1
ADRENAL CORTICES :	–	–	–	–	–	–	60	59
– Adenoma :	–	–	–	–	–	–	1	–
ADRENAL MEDULLAS :	–	–	–	–	–	–	59	59
– Pheochromocytoma b. :	–	–	–	–	–	–	9	15
– Pheochromocytoma m. :	–	–	–	–	–	–	6	3
HEMOLYMPHORET. SYS. :	–	–	–	–	–	–	60	60
– Malignant lymphoma :	–	–	–	–	–	–	3	3

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SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
SPLEEN :	-	-	-	-	-	-	59	60
- Hemangioma :	-	-	-	-	-	-	1	-
- Sarcoma, NOS :	-	-	-	-	-	-	1	-
THYMUS :	-	-	-	-	-	-	58	55
- Thymoma, lymph.,ben.:	-	-	-	-	-	-	-	1
MESENT. LYMPH NODE :	-	-	-	-	-	-	56	59
- Hemangiosarcoma :	-	-	-	-	-	-	1	1
MANDIBULAR GLANDS :	-	-	-	-	-	-	59	58
- Adenocarcinoma :	-	-	-	-	-	-	-	1
HARDERIAN GLANDS :	-	-	-	-	-	-	60	60
- Malignant schwannoma:	-	-	-	-	-	-	1	-
MAMMARY GLAND :	-	-	-	-	-	-	60	60
- Adenoma :	-	-	-	-	-	-	-	1
- Fibroadenoma :	-	-	-	-	-	-	3	-
SKIN/SUBCUTIS :	-	-	-	-	-	-	60	60
- Papilloma :	-	-	-	-	-	-	-	1
- Fibroma :	-	-	-	-	-	-	4	6
- Sebaceous adenoma :	-	-	-	-	-	-	1	-
- Granular cell tumor :	-	-	-	-	-	-	1	-
- Basal cell tumor :	-	-	-	-	-	-	4	1
- Lipoma :	-	-	-	-	-	-	-	1
- Keratoacanthoma :	-	-	-	-	-	-	11	8
- Trichofolliculoma :	-	-	-	-	-	-	1	-
- Lipofibroma :	-	-	-	-	-	-	-	1
- Squamous carcinoma :	-	-	-	-	-	-	1	-
- Sebaceous carcinoma :	-	-	-	-	-	-	1	-
- Basal cell carcinoma:	-	-	-	-	-	-	1	1
- Osteosarcoma :	-	-	-	-	-	-	1	-

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HARLAN-C11963

TEST ITEM : Control Data
TEST SYSTEM : RAT, 104-Week, Internal Test
SPONSOR : Harlan Laboratories

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DATE : 11-OCT-12
PathData©System V6.2d2

NUMBER OF ANIMALS WITH NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
BODY CAVITIES :	-	-	-	-	-	-	14	5
- Mesothelioma :	-	-	-	-	-	-	1	-
- Malignant schwannoma:	-	-	-	-	-	-	1	-
- Sarcoma, NOS :	-	-	-	-	-	-	1	-
ZYMBAL'S GLANDS :	-	-	-	-	-	-	53	51
- Zymbal's gland aden.:	-	-	-	-	-	-	1	-
- Zymbal's gland carc.:	-	-	-	-	-	-	-	1
- Metastatic carcinoma:	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
GENERAL OBSERVATIONS :	-	-	-	-	-	-	12	15
- Observation confirm.:	-	-	-	-	-	-	12	15
- No histological cor.:	-	-	-	-	-	-	-	1
CEREBRUM :	-	-	-	-	-	-	60	60
- Area of compression :	-	-	-	-	-	-	3	-
- Mineralization :	-	-	-	-	-	-	2	-
MEDULLA OBLONGATA :	-	-	-	-	-	-	60	60
- Nerve fiber degen. :	-	-	-	-	-	-	14	14
SPINAL CORD, CERVIC. :	-	-	-	-	-	-	60	60
- Radiculoneuropathy :	-	-	-	-	-	-	-	3
SPINAL CORD, THORAC. :	-	-	-	-	-	-	60	60
- Radiculoneuropathy :	-	-	-	-	-	-	10	14
SPINAL CORD, LUMBAR :	-	-	-	-	-	-	60	59
- Radiculoneuropathy :	-	-	-	-	-	-	28	27
SCIATIC NERVES :	-	-	-	-	-	-	60	60
- Vascular mineraliz. :	-	-	-	-	-	-	14	11
- Nerve fiber degen. :	-	-	-	-	-	-	56	51
HEART :	-	-	-	-	-	-	60	60
- Mineralization :	-	-	-	-	-	-	1	-
- Vascular mineraliz. :	-	-	-	-	-	-	3	-
- Mononuclear foci :	-	-	-	-	-	-	-	1
- Myocardial necrosis :	-	-	-	-	-	-	-	1
- Chr.prog.cardiomyop.:	-	-	-	-	-	-	47	45
- Endocardial hyperpl.:	-	-	-	-	-	-	-	1
AORTA :	-	-	-	-	-	-	60	60
- Mineralization :	-	-	-	-	-	-	3	-
- Inflammation :	-	-	-	-	-	-	1	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
NASOPHARYNGEAL DUCT :	-	-	-	-	-	-	60	60
- Hemorrhage :	-	-	-	-	-	-	1	2
- Secretion :	-	-	-	-	-	-	2	5
NASAL CAV.,LEVEL 1 :	-	-	-	-	-	-	60	60
- Food in lumen :	-	-	-	-	-	-	-	1
- Hyaline inclusions :	-	-	-	-	-	-	3	-
- Inflammatory secret.:	-	-	-	-	-	-	-	1
- Inflammation:submuc.:	-	-	-	-	-	-	-	1
- Epithelial degen. :	-	-	-	-	-	-	-	2
- Sero-mucinous secr. :	-	-	-	-	-	-	2	4
- Goblet cell prolif. :	-	-	-	-	-	-	-	1
NASAL CAV.,LEVEL 2 :	-	-	-	-	-	-	60	60
- Food in lumen :	-	-	-	-	-	-	-	2
- Hyaline inclusions :	-	-	-	-	-	-	10	11
- Respiratory hyperpl.:	-	-	-	-	-	-	2	2
- Sero-mucinous secr. :	-	-	-	-	-	-	9	5
- Inflammatory secret.:	-	-	-	-	-	-	-	1
- Inflammation, submu.:	-	-	-	-	-	-	1	2
- Epithelial degen. :	-	-	-	-	-	-	4	1
NASAL CAV.,LEVEL 3 :	-	-	-	-	-	-	60	60
- Sero-mucinous secr. :	-	-	-	-	-	-	2	2
- Inflammatory secret.:	-	-	-	-	-	-	-	2
- Inflammation :	-	-	-	-	-	-	1	1
- Hyaline inclusions :	-	-	-	-	-	-	22	22
- Submucosal inflamm. :	-	-	-	-	-	-	-	2
- Epithelial degener. :	-	-	-	-	-	-	1	3
- Resp.metap./hyperpl.:	-	-	-	-	-	-	1	-
- Fibro-osseous lesion:	-	-	-	-	-	-	1	-
NASAL CAV.,LEVEL 4 :	-	-	-	-	-	-	60	60
- Hyaline inclusions :	-	-	-	-	-	-	6	5
- Sero-mucinous secr. :	-	-	-	-	-	-	-	1
- Epithelial degener. :	-	-	-	-	-	-	2	-

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SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
LARYNX :	-	-	-	-	-	-	60	60
- Food in lumen :	-	-	-	-	-	-	-	3
- Hemorrhage :	-	-	-	-	-	-	2	1
- Dissecated secretion:	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	-	3
- Glandular inflamm. :	-	-	-	-	-	-	-	3
TRACHEA :	-	-	-	-	-	-	60	60
- Anomaly :	-	-	-	-	-	-	1	-
- Foreign material :	-	-	-	-	-	-	-	1
- Glandular dilation :	-	-	-	-	-	-	6	7
LUNG :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	3	3
- Foreign mat./food p.:	-	-	-	-	-	-	1	10
- Heterotopic muscle :	-	-	-	-	-	-	1	-
- Osseous metaplasia :	-	-	-	-	-	-	2	2
- Vascular mineraliz. :	-	-	-	-	-	-	48	49
- Alveolar mineraliz. :	-	-	-	-	-	-	1	-
- Congestion :	-	-	-	-	-	-	9	18
- Alveolar edema :	-	-	-	-	-	-	6	1
- Hemorrhage :	-	-	-	-	-	-	-	5
- Hemosiderin :	-	-	-	-	-	-	-	1
- Alveolar macrophages:	-	-	-	-	-	-	13	6
- Heart failure cells :	-	-	-	-	-	-	-	1
- Mononuclear foci :	-	-	-	-	-	-	-	2
- Fibrosis :	-	-	-	-	-	-	1	-
- Alveolitis :	-	-	-	-	-	-	7	-
- Granuloma(s) :	-	-	-	-	-	-	-	2
- Cholesterol granul. :	-	-	-	-	-	-	2	1
- Inflammation, inter.:	-	-	-	-	-	-	7	9
- Inflammation: bron. :	-	-	-	-	-	-	-	5

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: KO, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
TONGUE :	-	-	-	-	-	-	60	60
- Hyperkeratosis :	-	-	-	-	-	-	-	1
- Vascular mineraliz. :	-	-	-	-	-	-	2	-
- Myofiber degenerat. :	-	-	-	-	-	-	-	1
- Atrophy, saliv.gl. :	-	-	-	-	-	-	2	-
- Vacuolar deg.sal.gl.:	-	-	-	-	-	-	1	-
- Mononuclear foci :	-	-	-	-	-	-	2	-
- Peri-/arteritis :	-	-	-	-	-	-	3	-
TOOTH/TEETH :	-	-	-	-	-	-	60	60
- Odontoblast degener.:	-	-	-	-	-	-	2	1
- Dental dysplasia :	-	-	-	-	-	-	4	10
- Pulp denticle :	-	-	-	-	-	-	8	8
- Root inflammation :	-	-	-	-	-	-	1	-
- Pulp inflammation :	-	-	-	-	-	-	1	-
- Parodontal inflamm. :	-	-	-	-	-	-	9	7
- Incr.niche formation:	-	-	-	-	-	-	1	-
ESOPHAGUS :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	2
- Food in lumen :	-	-	-	-	-	-	2	2
- Dilation :	-	-	-	-	-	-	-	1
- Hyperkeratosis :	-	-	-	-	-	-	5	-

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :									MALE
DOSE GROUP:	01	02	03	04	05	06	07	08	
NO.ANIMALS:	-	-	-	-	-	-	60	60	
STOMACH :	-	-	-	-	-	-	60	60	
- No histological cor.:	-	-	-	-	-	-	2	3	
- Glandular dilation :	-	-	-	-	-	-	35	36	
- Congestion :	-	-	-	-	-	-	1	3	
- Mineralization :	-	-	-	-	-	-	5	-	
- Lymphoid follicles :	-	-	-	-	-	-	6	6	
- Peri-/arteritis :	-	-	-	-	-	-	2	1	
- Erosion(s) gland. :	-	-	-	-	-	-	3	1	
- Erosion(s) forest. :	-	-	-	-	-	-	1	-	
- Ulceration gland. :	-	-	-	-	-	-	1	-	
- Ulceration forest. :	-	-	-	-	-	-	2	-	
- Inflammation :	-	-	-	-	-	-	7	2	
- Squamous hyperplasia:	-	-	-	-	-	-	7	4	
- Hyperkeratosis :	-	-	-	-	-	-	3	2	
- Gland.mucosal degen.:	-	-	-	-	-	-	4	-	
- Regener.hyperplasia :	-	-	-	-	-	-	1	-	
DUODENUM :	-	-	-	-	-	-	60	60	
- No histological cor.:	-	-	-	-	-	-	1	1	
- Glandular dilation :	-	-	-	-	-	-	-	1	
- Mucosal atrophy :	-	-	-	-	-	-	1	-	
JEJUNUM :	-	-	-	-	-	-	60	59	
- No histological cor.:	-	-	-	-	-	-	2	2	
- Embryonic remnants :	-	-	-	-	-	-	-	1	
- Congestion :	-	-	-	-	-	-	1	-	
- Mucosal atrophy :	-	-	-	-	-	-	1	-	
ILEUM :	-	-	-	-	-	-	60	58	
- Observation confirm.:	-	-	-	-	-	-	-	1	
- No histological cor.:	-	-	-	-	-	-	3	-	
- Congestion :	-	-	-	-	-	-	1	-	
- Mucosal atrophy :	-	-	-	-	-	-	1	-	

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
PEYER'S P.-JEJUNUM :	-	-	-	-	-	-	56	57
- Peyer's patch :	-	-	-	-	-	-	-	1
- Observation confirm.:	-	-	-	-	-	-	2	2
- No histological cor.:	-	-	-	-	-	-	-	1
- Mineralization :	-	-	-	-	-	-	1	-
- Lymphoid atrophy :	-	-	-	-	-	-	1	-
- Lymphoid hyperplasia:	-	-	-	-	-	-	1	-
PEYER'S P.-ILEUM :	-	-	-	-	-	-	47	54
- Observation confirm.:	-	-	-	-	-	-	1	1
- Ductal remnants :	-	-	-	-	-	-	2	1
- Lymphoid atrophy :	-	-	-	-	-	-	1	-
CECUM :	-	-	-	-	-	-	60	58
- No histol.correlate :	-	-	-	-	-	-	3	1
- Mucosal atrophy :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	-	1
COLON :	-	-	-	-	-	-	60	58
- No histological cor.:	-	-	-	-	-	-	1	-
- Nematodes :	-	-	-	-	-	-	1	-
- Mucosal atrophy :	-	-	-	-	-	-	1	-
RECTUM :	-	-	-	-	-	-	60	58
- Nematodes :	-	-	-	-	-	-	4	1
- Mucosal atrophy :	-	-	-	-	-	-	1	-

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SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
LIVER :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	8	11
- Lobe torsion :	-	-	-	-	-	-	1	-
- Hepatodiaphrag.nod. :	-	-	-	-	-	-	2	-
- Congestion :	-	-	-	-	-	-	3	4
- Lymphangiectasis :	-	-	-	-	-	-	-	1
- Hemosiderin :	-	-	-	-	-	-	1	-
- Kupffer's cell pigm.:	-	-	-	-	-	-	1	-
- Erythropoiesis :	-	-	-	-	-	-	3	1
- Hepatocel.hypertr. :	-	-	-	-	-	-	2	2
- Inflammatory foci :	-	-	-	-	-	-	14	16
- Focal fibrosis :	-	-	-	-	-	-	3	-
- Peribiliary fibrosis:	-	-	-	-	-	-	19	20
- Peribiliar inflamm. :	-	-	-	-	-	-	4	8
- Bile duct prolifer. :	-	-	-	-	-	-	25	34
- Spongiosis hepatis :	-	-	-	-	-	-	2	3
- Glycogen stor.incr. :	-	-	-	-	-	-	1	-
- Fatty change :	-	-	-	-	-	-	17	12
- Vacuolated foci :	-	-	-	-	-	-	7	4
- Hepatocel.degener. :	-	-	-	-	-	-	1	-
- Arterial med.hypert.:	-	-	-	-	-	-	1	-
- Peri-/arteritis :	-	-	-	-	-	-	1	-
- Necrosis, coagul. :	-	-	-	-	-	-	-	1
- Clear cell foci :	-	-	-	-	-	-	24	33
- Basophilic foci :	-	-	-	-	-	-	4	2
- Eosinophilic foci :	-	-	-	-	-	-	1	1

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TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
PANCREAS :	-	-	-	-	-	-	58	60
- No histological cor.:	-	-	-	-	-	-	3	3
- Congestion :	-	-	-	-	-	-	5	1
- Edema, interstitial :	-	-	-	-	-	-	3	-
- Hemosiderin: islets :	-	-	-	-	-	-	2	1
- Hemosiderin: exocr. :	-	-	-	-	-	-	1	7
- Vacuolation :	-	-	-	-	-	-	2	5
- Exocrine atrophy :	-	-	-	-	-	-	8	9
- Ductal proliferation:	-	-	-	-	-	-	1	-
- Mononuclear foci :	-	-	-	-	-	-	-	1
- Peri-/arteritis :	-	-	-	-	-	-	7	3
- Inflammation :	-	-	-	-	-	-	-	1
- Exocrine hyperplasia:	-	-	-	-	-	-	3	8
- Islet cell hyperpl. :	-	-	-	-	-	-	3	6
KIDNEYS :	-	-	-	-	-	-	60	60
- Congestion :	-	-	-	-	-	-	-	1
- Pelvic dilation :	-	-	-	-	-	-	-	1
- Hydronephrosis :	-	-	-	-	-	-	1	2
- Hemosiderin :	-	-	-	-	-	-	-	1
- Hyaline droplets :	-	-	-	-	-	-	2	1
- Cortical mineraliz. :	-	-	-	-	-	-	-	1
- Medullar mineraliz. :	-	-	-	-	-	-	1	3
- Pelvic mineraliz. :	-	-	-	-	-	-	5	3
- Papillary mineraliz.:	-	-	-	-	-	-	-	1
- Tubular basophilia :	-	-	-	-	-	-	2	2
- Tubular casts :	-	-	-	-	-	-	5	3
- Abscess :	-	-	-	-	-	-	15	9
- Thrombosis :	-	-	-	-	-	-	1	-
- Scaring (infarct) :	-	-	-	-	-	-	2	-
- Pyelonephritis :	-	-	-	-	-	-	1	2
- Chronic nephropathy :	-	-	-	-	-	-	52	53
- Telangiectasis :	-	-	-	-	-	-	2	2
- Urothelial hyperpl. :	-	-	-	-	-	-	19	20
- Tubular hypertrophy :	-	-	-	-	-	-	1	-
- Tubular proliferat. :	-	-	-	-	-	-	17	15

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SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
URETERS :	-	-	-	-	-	-	60	59
- Dilation :	-	-	-	-	-	-	3	2
- Urothelial hyperpl. :	-	-	-	-	-	-	-	1
- Inflammation :	-	-	-	-	-	-	1	-
URINARY BLADDER :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	1	-
- Proteinaceous plug :	-	-	-	-	-	-	2	-
- Distension :	-	-	-	-	-	-	4	3
- Congestion :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	4	2
- Urothelial hypertr. :	-	-	-	-	-	-	1	1
- Urothelial hyperpl. :	-	-	-	-	-	-	2	1
TESTES :	-	-	-	-	-	-	59	60
- Congestion :	-	-	-	-	-	-	1	-
- Edema, interstitial :	-	-	-	-	-	-	1	4
- Edema, tubular :	-	-	-	-	-	-	1	-
- Mineralization :	-	-	-	-	-	-	1	3
- Tubular degeneration:	-	-	-	-	-	-	32	27
- Multinuc.giant cells:	-	-	-	-	-	-	3	-
- Sperm stasis :	-	-	-	-	-	-	1	1
- Peri-/arteritis :	-	-	-	-	-	-	29	23
- Leydig cell hyperpl.:	-	-	-	-	-	-	1	1
EPIDIDYMIDES :	-	-	-	-	-	-	59	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Edema :	-	-	-	-	-	-	1	-
- Cellular detritus :	-	-	-	-	-	-	7	10
- Tubular degeneration:	-	-	-	-	-	-	7	8
- Epithelial vacuol. :	-	-	-	-	-	-	1	1
- Oligospermia :	-	-	-	-	-	-	3	6
- Aspermia :	-	-	-	-	-	-	7	8
- Mononuclear foci :	-	-	-	-	-	-	4	3
- Peri-/arteritis :	-	-	-	-	-	-	1	2

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
PROSTATE GLAND :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Reduced colloid :	-	-	-	-	-	-	-	1
- Abscess :	-	-	-	-	-	-	-	1
- Inflammation :	-	-	-	-	-	-	9	6
- Epithelial atrophy :	-	-	-	-	-	-	3	-
COAGULATING GLANDS :	-	-	-	-	-	-	60	60
- Epithelial atrophy :	-	-	-	-	-	-	6	-
- Inflammation :	-	-	-	-	-	-	2	3
SEMINAL VESICLES :	-	-	-	-	-	-	60	60
- Congestion :	-	-	-	-	-	-	-	1
- Reduced colloid :	-	-	-	-	-	-	4	7
- Dilated acini :	-	-	-	-	-	-	1	-
- Capsular fibrosis :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	1	3
- Epithelial atrophy :	-	-	-	-	-	-	5	-
PREPUTIAL GLANDS :	-	-	-	-	-	-	2	2
- Dilation/atrophy :	-	-	-	-	-	-	2	-
- Inflammation :	-	-	-	-	-	-	-	1
PITUITARY GLAND :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Stomatodeal remnants:	-	-	-	-	-	-	1	-
- Vacuolated cells :	-	-	-	-	-	-	1	-
- Cyst(s):p.anterior :	-	-	-	-	-	-	6	7
- Cyst(s):p.intermedia:	-	-	-	-	-	-	2	2
- Hypertrophy: p.anter:	-	-	-	-	-	-	-	1
- Hyperpl.p.ant.focal :	-	-	-	-	-	-	10	7

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
THYROID GLAND :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	1	1
- Anomaly :	-	-	-	-	-	-	1	-
- Ductal remnants :	-	-	-	-	-	-	7	10
- Follicular cyst :	-	-	-	-	-	-	1	-
- Follicular dilation :	-	-	-	-	-	-	3	-
- C-cell hyperpl.focal:	-	-	-	-	-	-	8	4
- C-cell hyperpl.diff.:	-	-	-	-	-	-	1	4
- Foll.hyperpl.diff. :	-	-	-	-	-	-	1	2
- Foll.hyperpl.focal :	-	-	-	-	-	-	-	1
- Peri-/arteritis :	-	-	-	-	-	-	1	1
PARATHYROID GLANDS :	-	-	-	-	-	-	53	56
- Hyperplasia diffuse :	-	-	-	-	-	-	9	7
- Hyperplasia focal :	-	-	-	-	-	-	6	8
ADRENAL CORTICES :	-	-	-	-	-	-	60	59
- No histological cor.:	-	-	-	-	-	-	1	2
- Congestion :	-	-	-	-	-	-	-	1
- Extra-adrenal tissue:	-	-	-	-	-	-	9	8
- Fatty change:diffuse:	-	-	-	-	-	-	10	12
- Fatty change:focal :	-	-	-	-	-	-	19	20
- Cystic degeneration :	-	-	-	-	-	-	4	3
- Angiectasis :	-	-	-	-	-	-	-	2
- Peri-/arteritis :	-	-	-	-	-	-	-	1
- Atrophy :	-	-	-	-	-	-	1	-
- Diffuse hypertrophy :	-	-	-	-	-	-	5	8
- Hypertr.focal:glom. :	-	-	-	-	-	-	40	40
- Hypertr.focal:fasc. :	-	-	-	-	-	-	7	2
- Focal hyperplasia :	-	-	-	-	-	-	36	26
ADRENAL MEDULLAS :	-	-	-	-	-	-	59	59
- Hyperplasia diffuse :	-	-	-	-	-	-	2	-
- Hyperplasia focal :	-	-	-	-	-	-	16	12

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SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
SPLEEN :	-	-	-	-	-	-	59	60
- No histological cor.:	-	-	-	-	-	-	-	1
- Misshapen :	-	-	-	-	-	-	-	1
- Accessory spleen :	-	-	-	-	-	-	-	1
- Hemorrhage :	-	-	-	-	-	-	1	-
- Erythropoiesis :	-	-	-	-	-	-	52	55
- Histiocytosis :	-	-	-	-	-	-	-	1
- Hemosiderin :	-	-	-	-	-	-	51	53
- Fibrosis: capsular :	-	-	-	-	-	-	-	1
- Lymphoid hyperplasia:	-	-	-	-	-	-	2	2
- Lymphoid atrophy :	-	-	-	-	-	-	10	6
- Lymphangiectasis :	-	-	-	-	-	-	1	-
- Necrosis :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	-	1
BONE MARROW-FEMORAL :	-	-	-	-	-	-	60	60
- Increased erythrop. :	-	-	-	-	-	-	4	1
- Increased granulopo.:	-	-	-	-	-	-	5	4
- Hypocellularity :	-	-	-	-	-	-	44	50
- Myelostromal prolif.:	-	-	-	-	-	-	1	-
BONE MARROW-STERNAL :	-	-	-	-	-	-	59	60
- Increased erythrop. :	-	-	-	-	-	-	5	2
- Increased granulopo.:	-	-	-	-	-	-	21	17
- Increased fatty rep.:	-	-	-	-	-	-	1	-
- Hypocellularity :	-	-	-	-	-	-	8	22
- Myelostromal prolif.:	-	-	-	-	-	-	2	2
THYMUS :	-	-	-	-	-	-	58	55
- Congestion/hemorrh. :	-	-	-	-	-	-	7	16
- Cyst(s) :	-	-	-	-	-	-	3	4
- Hemosiderin :	-	-	-	-	-	-	-	1
- Involution/Atrophy :	-	-	-	-	-	-	55	50
- Epithelial hyperpl. :	-	-	-	-	-	-	4	5
- Peri-/arteritis :	-	-	-	-	-	-	2	-
- Inflammation :	-	-	-	-	-	-	-	1

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SUMMARY TABLES HARLAN--C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
LYMPH NODES :	-	-	-	-	-	-	10	13
- No histological cor.:	-	-	-	-	-	-	1	1
- Congestion :	-	-	-	-	-	-	4	9
- Hemosiderin :	-	-	-	-	-	-	3	4
- Plasma cells :	-	-	-	-	-	-	-	3
- Sinusoidal dilation :	-	-	-	-	-	-	5	4
- Necrosis :	-	-	-	-	-	-	1	-
- Fibrosis :	-	-	-	-	-	-	-	1
MESENT. LYMPH NODE :	-	-	-	-	-	-	56	59
- Congestion :	-	-	-	-	-	-	3	2
- Hemosiderin :	-	-	-	-	-	-	5	4
- Pigment-laden hist. :	-	-	-	-	-	-	44	48
- Plasma cells :	-	-	-	-	-	-	1	-
- Histiocytosis :	-	-	-	-	-	-	-	1
- Angiectasis :	-	-	-	-	-	-	1	1
- Lymphoid hyperplasia:	-	-	-	-	-	-	-	1
- Stromal cell hyperp.:	-	-	-	-	-	-	-	1
POPLITEAL LNN. :	-	-	-	-	-	-	59	59
- No histological cor.:	-	-	-	-	-	-	-	1
- Congestion :	-	-	-	-	-	-	4	5
- Hemosiderin :	-	-	-	-	-	-	-	3
- Activation :	-	-	-	-	-	-	1	3
- Plasma cells :	-	-	-	-	-	-	-	1
- Lymphoid atrophy :	-	-	-	-	-	-	1	-
MANDIB.LYMPH NODES :	-	-	-	-	-	-	59	58
- Congestion :	-	-	-	-	-	-	14	11
- Hemosiderin :	-	-	-	-	-	-	1	-
- Plasma cells :	-	-	-	-	-	-	39	45
- Activation :	-	-	-	-	-	-	1	-
- Lymphoid hyperplasia:	-	-	-	-	-	-	5	4
- Lymphoid atrophy :	-	-	-	-	-	-	1	-
- Sinusoidal dilation :	-	-	-	-	-	-	9	5
- Fibrosis :	-	-	-	-	-	-	2	-
- Stromal prolifer. :	-	-	-	-	-	-	1	-

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SUMMARY TABLES HARLAN-C11963

TEST ITEM : Control Data *PATHOL. NO.*: 41968 WEK
TEST SYSTEM : RAT, 104-Week, Internal Test *DATE* : 11-OCT-12
SPONSOR : Harlan Laboratories *PathData©System V6.2d2*

NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
SUBLINGUAL GLANDS :	-	-	-	-	-	-	59	57
- Acinar atrophy :	-	-	-	-	-	-	1	-
- Inflammation :	-	-	-	-	-	-	-	1
HARDERIAN GLANDS :	-	-	-	-	-	-	60	60
- Hemorrhage :	-	-	-	-	-	-	1	1
- Porphyrin deposition:	-	-	-	-	-	-	56	58
- Acinar dilation :	-	-	-	-	-	-	3	4
- Glandular atrophy :	-	-	-	-	-	-	1	-
- Mononuclear foci :	-	-	-	-	-	-	1	1
- Inflammation :	-	-	-	-	-	-	1	1
- Hyperplasia :	-	-	-	-	-	-	3	-
EXORBITAL LACR.GLDS. :	-	-	-	-	-	-	60	60
- Porphyrin deposition:	-	-	-	-	-	-	49	43
- Harderian alteration:	-	-	-	-	-	-	58	56
- Acinar hypertrophy :	-	-	-	-	-	-	-	1
- Mononuclear foci :	-	-	-	-	-	-	1	3
- Inflammation :	-	-	-	-	-	-	16	19
- Glandular atrophy :	-	-	-	-	-	-	1	-
MAMMARY GLAND :	-	-	-	-	-	-	60	60
- Subcutan.tiss.only :	-	-	-	-	-	-	7	7
- Secretion :	-	-	-	-	-	-	1	1
- Dilated ducts :	-	-	-	-	-	-	1	1
- Galactocele :	-	-	-	-	-	-	1	-
- Ceroid pigment :	-	-	-	-	-	-	-	1
- Granuloma :	-	-	-	-	-	-	1	-
- Glandular hyperpl. :	-	-	-	-	-	-	1	-

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SUMMARY TABLES HARLAN-C11963

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
SKIN/SUBCUTIS :	-	-	-	-	-	-	60	60
- No histological cor.:	-	-	-	-	-	-	1	4
- Dilated hair follic.:	-	-	-	-	-	-	-	1
- Inclusion cyst :	-	-	-	-	-	-	1	1
- Adnexal atrophy :	-	-	-	-	-	-	2	-
- Edema :	-	-	-	-	-	-	1	-
- Subcutan.adipose pad:	-	-	-	-	-	-	-	1
- Inflammation dermal :	-	-	-	-	-	-	1	-
- Intradermal fibrosis:	-	-	-	-	-	-	-	3
- Epidermal hyperpl. :	-	-	-	-	-	-	1	-
- Basal cell hyperpl. :	-	-	-	-	-	-	1	-
- Intracutan.keratosis:	-	-	-	-	-	-	-	1
- Sebaceous hyperpl. :	-	-	-	-	-	-	1	-
SKELETAL MUSCLE :	-	-	-	-	-	-	60	59
- Vascular mineraliz. :	-	-	-	-	-	-	1	-
- Myofiber degener. :	-	-	-	-	-	-	6	2
- Peri-/arteritis :	-	-	-	-	-	-	1	-
BONE :	-	-	-	-	-	-	2	3
- No histological cor.:	-	-	-	-	-	-	2	2
- Tibial physis hyper.:	-	-	-	-	-	-	-	1
JOINTS :	-	-	-	-	-	-	60	60
- Inflammation :	-	-	-	-	-	-	-	1
EYES :	-	-	-	-	-	-	59	60
- No histological cor.:	-	-	-	-	-	-	3	1
- Hemorrhage :	-	-	-	-	-	-	7	5
- Lenticular degener. :	-	-	-	-	-	-	2	-
- Inflammation orbit. :	-	-	-	-	-	-	5	2
- Corneal epith.degen.:	-	-	-	-	-	-	-	1
- Corneal hyperplasia :	-	-	-	-	-	-	3	-
- Corneal hyperkerat. :	-	-	-	-	-	-	-	2
- Corneal dystrophy :	-	-	-	-	-	-	1	4
- Keratitis :	-	-	-	-	-	-	13	5
- Phtisis bulbi :	-	-	-	-	-	-	1	1

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NUMBER OF ANIMALS WITH NON-NEOPLASTIC LESIONS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCL. DEATHS

SEX :								MALE
DOSE GROUP:	01	02	03	04	05	06	07	08
NO.ANIMALS:	-	-	-	-	-	-	60	60
BODY CAVITIES :	-	-	-	-	-	-	14	5
- No histological cor.:	-	-	-	-	-	-	1	1
- Hemorrhage :	-	-	-	-	-	-	-	1
- Congestion :	-	-	-	-	-	-	1	-
- Fat necrosis :	-	-	-	-	-	-	2	2
- Peri-/arteritis :	-	-	-	-	-	-	1	-
CAUSE DEATH/MORBID. :	-	-	-	-	-	-	41	39
- Chronic nephropathy :	-	-	-	-	-	-	23	16
- Chronic cardiomyop. :	-	-	-	-	-	-	8	6
- Inflammation/Necros.:	-	-	-	-	-	-	3	2
- Systemic neoplasia :	-	-	-	-	-	-	3	2
- Pituitary neoplasm :	-	-	-	-	-	-	3	-
- Pheochromocytoma :	-	-	-	-	-	-	4	1
- Other tumors :	-	-	-	-	-	-	10	8
- Unknown :	-	-	-	-	-	-	5	12
ZYMBAL'S GLANDS :	-	-	-	-	-	-	53	51
- Abscess :	-	-	-	-	-	-	1	-
- Hyperplasia :	-	-	-	-	-	-	-	1
FEMUR :	-	-	-	-	-	-	60	60
- Osteoporosis :	-	-	-	-	-	-	2	-
- Osteopetrosis :	-	-	-	-	-	-	2	-
- Fibrous osteodystr. :	-	-	-	-	-	-	1	1
STERNUM :	-	-	-	-	-	-	60	60
- Chondromuc.degener. :	-	-	-	-	-	-	8	18
- Fibrous osteodystr. :	-	-	-	-	-	-	2	-
- Osteopetrosis :	-	-	-	-	-	-	2	-
- Osteoporosis :	-	-	-	-	-	-	-	1

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