

Appendix 5 Blood Chemistry

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Total Cholesterol (mg/dL)	Phospholipid (mg/dL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	111	102	.	.	.	.	166	164	.	.	.	.
50402	127	127	166	.	.	.	192	190	322	.	.	.
50403	121	129	.	.	118	.	151	154	.	.	162	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	49	86	.	.	.	.	7.9	8.2	.	.	.	.
50402	11	13	90	.	.	.	8.4	7.6	10.8	.	.	.
50403	29	53	.	.	56	.	7.9	8.1	.	.	7.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	9.9	10.6	.	.	.	.	5.1	4.6	.	.	.	.
50402	11.6	10.3	9.9	.	.	.	5.5	5.6	21.4 <sup>1</sup>	.	.	.
50403	10.4	10.2	.	.	10.1	.	4.7	4.7	.	.	2.2	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

1 [RC:Re-analysis due to sample outside of the assay range]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Na	Na	Na	Na	Na	Na	K	K	K	K	K	K
	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	154	157	.	.	.	.	5.3	5.5	.	.	.	.
50402	161	155	138	.	.	.	7.0	5.4	8.7	.	.	.
50403	153	154	.	.	149	.	5.0	5.3	.	.	6.4	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Cl	Cl	Cl	Cl	Cl	Cl	A/G Ratio					
	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)						
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	112	115	.	.	.	.	1.23	1.34	.	.	.	.
50402	115	114	87	.	.	.	1.40	1.45	0.98	.	.	.
50403	112	115	.	.	108	.	1.38	1.41	.	.	1.29	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin	Albumin
	(%)	(%)	(%)	(%)	(%)	(%)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	55.2	57.2	.	.	.	.	4.4	4.7	.	.	.	.
50402	58.4	59.2	49.6	.	.	.	4.9	4.5	5.3	.	.	.
50403	57.9	58.5	.	.	56.4	.	4.6	4.7	.	.	4.1	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Alpha1 Globulin (%)	Alpha2 Globulin (%)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	3.9	2.8	.	.	.	.	10.0	10.3	.	.	.	.
50402	3.5	3.2	9.8	.	.	.	11.4	11.1	14.1	.	.	.
50403	3.2	2.9	.	.	4.4	.	8.1	9.1	.	.	9.9	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Beta Globulin (%)	Gamma Globulin (%)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	15.4	15.7	.	.	.	.	15.5	14.0	.	.	.	.
50402	12.6	12.5	16.1	.	.	.	14.1	14.0	10.4	.	.	.
50403	16.2	16.6	.	.	17.5	.	14.6	12.9	.	.	11.8	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Alpha1 Globulin (g/dL)	Alpha2 Globulin (g/dL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	0.3	0.2	.	.	.	.	0.8	0.8	.	.	.	.
50402	0.3	0.2	1.1	.	.	.	1.0	0.8	1.5	.	.	.
50403	0.3	0.2	.	.	0.3	.	0.6	0.7	.	.	0.7	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

Appendix 5 Blood Chemistry

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Sex: Female Day(s) Relative to Start Date

500 mg/kg	Blood Chemistry											
	Beta Globulin (g/dL)	Gamma Globulin (g/dL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	1.2	1.3	.	.	.	.	1.2	1.1	.	.	.	.
50402	1.1	1.0	1.7	.	.	.	1.2	1.1	1.1	.	.	.
50403	1.3	1.3	.	.	1.3	.	1.2	1.0	.	.	0.9	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^3%)	Thyroids (mg)	Thyroids Ratio (^3%)	Thymus (g)	Thymus Ratio (^3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10101	3.4	66.9	1.968	54	1.59	293	8.62	249	7.32	542	15.94	3.63	106.8
10102	3.3	69.3	2.100	55	1.67	221	6.70	192	5.82	413	12.52	2.65	80.3
10103	3.1	65.0	2.097	48	1.55	165	5.32	172	5.55	337	10.87	2.68	86.5

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10101	0.72	21.2	0.76	22.4	1.48	43.5	16.58	0.488	13.67	0.402	51.6	1.52	4.24
10102	1.58	47.9	1.55	47.0	3.13	94.8	17.92	0.543	9.37	0.284	47.7	1.45	2.49
10103	1.14	36.8	1.49	48.1	2.63	84.8	13.48	0.435	9.44	0.305	48.4	1.56	2.01

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L)Ratio (%)	Kidney (R) (g)	Kidney (R)Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L)Ratio (^-3%)	Adrenal (R) (mg)	Adrenal (R)Ratio (^-3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10101	0.125	5.73	0.169	5.21	0.153	5.43	0.160	10.64	0.313	327	9.62	243	7.15
10102	0.075	7.22	0.219	5.92	0.179	6.11	0.185	12.03	0.365	249	7.55	188	5.70
10103	0.065	5.31	0.171	4.52	0.146	4.55	0.147	9.07	0.293	181	5.84	135	4.35

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Adrenals (mg)	Adrenals Ratio (^-3%)	Testis (L) (g)	Testis (L)Ratio (^-3%)	Testis (R) (g)	Testis (R)Ratio (^-3%)	Testes (g)	Testes Ratio (^-3%)	Prostate (g)	Prostate Ratio (^-3%)	Seminal vesicle (g)	Seminal ves. Ratio (^-3%)	Epididymis (L) (g)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10101	570	16.76	0.93	27.4	0.91	26.8	1.84	54.1	0.94	27.6	1.96	57.6	0.78
10102	437	13.24	3.84	116.4	3.43	103.9	7.27	220.3	0.66	20.0	1.47	44.5	0.86
10103	316	10.19	0.46	14.8	0.34	11.0	0.80	25.8	0.64	20.6	1.05	33.9	0.45

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)				
	Epididymis (L)Ratio (^3%)	Epididymis (R) (g)	Epididymis (R)Ratio (^3%)	Epididymides (g)	Epididymides Ratio (^3%)
	15	15	15	15	15
10101	22.9	0.75	22.1	1.53	45.0
10102	26.1	0.78	23.6	1.64	49.7
10103	14.5	0.48	15.5	0.93	30.0

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^3%)	Thyroids (mg)	Thyroids Ratio (^3%)	Thymus (g)	Thymus Ratio (^3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10201	2.8	65.4	2.336	58	2.07	96	3.43	95	3.39	191	6.82	0.88	31.4
10202	3.4	62.1	1.826	70	2.06	283	8.32	347	10.21	630	18.53	1.96	57.6
10203	3.2	67.8	2.119	90	2.81	258	8.06	242	7.56	500	15.63	1.54	48.1

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10201	1.23	43.9	1.29	46.1	2.52	90.0	14.91	0.533	7.67	0.274	51.8	1.85	2.00
10202	0.75	22.1	0.64	18.8	1.39	40.9	16.13	0.474	10.61	0.312	69.5	2.04	2.47
10203	1.82	56.9	1.66	51.9	3.48	108.8	15.55	0.486	11.42	0.357	53.8	1.68	2.57

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L)Ratio (%)	Kidney (R) (g)	Kidney (R)Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L)Ratio (^-3%)	Adrenal (R) (mg)	Adrenal (R)Ratio (^-3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10201	0.071	4.64	0.166	5.96	0.213	6.05	0.216	12.01	0.429	322	11.50	219	7.82
10202	0.073	6.47	0.190	5.70	0.168	5.49	0.161	11.19	0.329	230	6.76	160	4.71
10203	0.080	7.85	0.245	6.11	0.191	6.72	0.210	12.83	0.401	289	9.03	204	6.38

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)												
	Adrenals (mg)	Adrenals Ratio (^-3%)	Testis (L) (g)	Testis (L)Ratio (^-3%)	Testis (R) (g)	Testis (R)Ratio (^-3%)	Testes (g)	Testes Ratio (^-3%)	Prostate (g)	Prostate Ratio (^-3%)	Seminal vesicle (g)	Seminal ves. Ratio (^-3%)	Epididymis (L) (g)
	15	15	15	15	15	15	15	15	15	15	15	15	15
10201	541	19.32	1.85	66.1	2.01	71.8	3.86	137.9	1.93	68.9	1.17	41.8	0.46
10202	390	11.47	1.24	36.5	1.23	36.2	2.47	72.6	0.98	28.8	1.34	39.4	0.64
10203	493	15.41	1.27	39.7	1.12	35.0	2.39	74.7	0.94	29.4	1.47	45.9	0.63

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)				
	Epididymis (L)Ratio (^3%)	Epididymis (R) (g)	Epididymis (R)Ratio (^3%)	Epididymides (g)	Epididymides Ratio (^3%)
	15	15	15	15	15
10201	16.4	0.52	18.6	0.98	35.0
10202	18.8	0.72	21.2	1.36	40.0
10203	19.7	0.59	18.4	1.22	38.1

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5. ]