

Appendix 6

Organ Weight

B120719

Sex: Female 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
50202	0.81	32.4	0.80	32.0	1.61	64.4	17.78	0.711	8.68	0.347	52.0	2.08	1.18
50203	0.68	26.2	0.70	26.9	1.38	53.1	15.52	0.597	8.97	0.345	64.7	2.49	2.09

[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

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
50202	0.047	3.92	0.157	5.36	0.214	5.67	0.227	11.03	0.441	358	14.32	257	10.28
50203	0.080	4.80	0.185	6.67	0.257	6.59	0.253	13.26	0.510	391	15.04	301	11.58

[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

50 mg/kg	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	15	15	15	15	15	15	15	15	15	15
50202	615	24.60	130	5.20	76	3.04	206	8.24	6.45	258.0
50203	692	26.62	85	3.27	159	6.12	244	9.38	5.93	228.1

[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

150 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
50301	2.2	62.5	2.841	64	2.91	129	5.86	143	6.50	272	12.36	0.45	20.5
50302	2.7	70.1	2.596	68	2.52	250	9.26	212	7.85	462	17.11	0.38	14.1

[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

150 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
50301	0.78	35.5	0.92	41.8	1.70	77.3	12.96	0.589	8.29	0.377	48.6	2.21	1.58
50302	1.04	38.5	1.14	42.2	2.18	80.7	13.85	0.513	9.16	0.339	59.2	2.19	2.08

[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

150 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
50301	0.072	5.95	0.270	3.94	0.179	3.96	0.180	7.90	0.359	385	17.50	317	14.41
50302	0.077	5.69	0.211	5.47	0.203	5.48	0.203	10.95	0.406	211	7.81	136	5.04

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

Appendix 6 Organ Weight

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Sex: Female Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	15	15	15	15	15	15	15	15	15	15
50301	702	31.91	121	5.50	135	6.14	256	11.64	3.13	142.3
50302	347	12.85	74	2.74	65	2.41	139	5.15	3.53	130.7

[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	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%)
	11	11	11	11	11	11	11	11	11	11	11	11	11
50403	2.9	59.1	2.038	67	2.31	222	7.66	250	8.62	472	16.28	0.88	30.3

[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	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)
	11	11	11	11	11	11	11	11	11	11	11	11	11
50403	1.22	42.1	1.20	41.4	2.42	83.4	14.53	0.501	9.37	0.323	67.7	2.33	2.67

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

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Organ Weight

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Sex: Female Day(s) Relative to Start Date

500 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%)
	11	11	11	11	11	11	11	11	11	11	11	11	11
50403	0.092	5.76	0.199	5.74	0.198	6.49	0.224	12.23	0.422	289	9.97	267	9.21

[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	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	11	11	11	11	11	11	11	11	11	11
50403	556	19.17	130	4.48	205	7.07	335	11.55	5.94	204.8

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

Sex: Female 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%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50201	2.6	67.5	2.596	59	2.27	253	9.73	275	10.58	528	20.31	0.51	19.6

[MOR : Death or 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

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)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50201	0.35	13.5	0.62	23.8	0.97	37.3	12.17	0.468	9.00	0.346	58.7	2.26	2.54

[MOR : Death or 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

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%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50201	0.098	4.20	0.162	5.38	0.207	5.38	0.207	10.76	0.414	486	18.69	369	14.19

[MOR : Death or 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

50 mg/kg	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50201	855	32.88	127	4.88	109	4.19	236	9.08	6.21	238.8

[MOR : Death or Moribundity.]

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

Sex: Female Day(s) Relative to Start Date

150 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%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50303	2.8	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or 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

150 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)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50303	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or 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

150 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%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50303	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Sex: Female Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50303	-	-	-	-	-	-	-	-	-	-

[MOR : Death or 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	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%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50401	2.6	-	-	-	-	-	-	-	-	-	-	-	-
50402	2.5	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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