

Appendix 9

Organ Weight

B130235

Sex: Male Day(s) Relative to Start Date

30 mg/kg	Organ Weights (Monkey)													
	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%)	Adrenals (mg)	Adrenals Ratio (^-3%)	Testis (L) (g)	Testis (L)Ratio (^-3%)	Testis (R) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
10401	0.159	8.08	0.158	16.18	0.317	320	6.27	253	4.96	573	11.24	16.10	315.7	17.50
10402	0.184	10.08	0.183	20.22	0.368	321	5.84	271	4.93	592	10.76	28.69	521.6	17.32

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Sex: Male Day(s) Relative to Start Date

30 mg/kg	Organ Weights (Monkey)						
	Testis (R)Ratio (^3%)	Testes (g)	Testes Ratio (^3%)	Prostate (g)	Prostate Ratio (^3%)	Seminal vesicle (g)	Seminal ves. Ratio (^3%)
	29	29	29	29	29	29	29
10401	343.1	33.60	658.8	2.63	51.6	3.81	74.7
10402	314.9	46.01	836.5	3.83	69.6	9.53	173.3

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Organ Weight

B130235

Sex: Female 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%)	Submand. GL (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50101	4.2	63.3	1.507	60	1.43	172	4.10	155	3.69	327	7.79	2.42	57.6	0.92
50102	3.5	68.3	1.951	61	1.74	269	7.69	299	8.54	568	16.23	2.25	64.3	1.70

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Organ Weight

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)													
	Submand. GL (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GL (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)	Spleen Ratio (%)	Kidney (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50101	21.9	0.93	22.1	1.85	44.0	19.40	0.462	15.88	0.378	68.1	1.62	3.66	0.087	5.77
50102	48.6	1.73	49.4	3.43	98.0	19.16	0.547	12.15	0.347	57.9	1.65	2.98	0.085	6.69

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)													
	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%)	Adrenals (mg)	Adrenals Ratio (^-3%)	Ovary (L) (mg)	Ovary (L)Ratio (^-3%)	Ovary (R) (mg)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50101	0.137	5.74	0.137	11.51	0.274	272	6.48	267	6.36	539	12.83	277	6.60	210
50102	0.191	6.60	0.189	13.29	0.380	293	8.37	238	6.80	531	15.17	206	5.89	154

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Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)				
	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	29	29	29	29	29
50101	5.00	487	11.60	12.05	286.9
50102	4.40	360	10.29	7.81	223.1

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Sex: Female Day(s) Relative to Start Date

1 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%)	Submand. GL (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50201	3.6	63.4	1.761	64	1.78	246	6.83	229	6.36	475	13.19	1.37	38.1	0.77
50202	4.9	67.4	1.376	65	1.33	5142	104.94	367	7.49	5509	112.43	4.90	100.0	1.65

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Sex: Female Day(s) Relative to Start Date

1 mg/kg	Organ Weights (Monkey)													
	Submand. GL (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GL (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)	Spleen Ratio (%)	Kidney (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50201	214	0.86	23.9	1.63	45.3	18.63	0.518	12.21	0.339	60.6	1.68	2.43	0.068	5.31
50202	33.7	1.38	28.2	3.03	61.8	18.71	0.382	14.60	0.298	71.7	1.46	2.54	0.052	9.20

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Sex: Female Day(s) Relative to Start Date

1 mg/kg	Organ Weights (Monkey)													
	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%)	Adrenals (mg)	Adrenals Ratio (^3%)	Ovary (L) (mg)	Ovary (L)Ratio (^3%)	Ovary (R) (mg)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50201	0.148	5.54	0.154	10.85	0.301	321	8.92	272	7.56	593	16.47	304	8.44	155
50202	0.188	8.66	0.177	17.86	0.364	247	5.04	278	5.67	525	10.71	144	2.94	359

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Sex: Female Day(s) Relative to Start Date

1 mg/kg	Organ Weights (Monkey)				
	Ovary (R)Ratio ([^] -3%)	Ovaries (mg)	Ovaries Ratio ([^] -3%)	Uterus (g)	Uterus Ratio ([^] -3%)
	29	29	29	29	29
50201	4.31	459	12.75	6.31	175.3
50202	7.33	503	10.27	6.33	129.2

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Sex: Female Day(s) Relative to Start Date

10 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%)	Submand. GL (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50301	4.0	65.9	1.648	99	2.48	266	6.65	238	5.95	504	12.60	2.28	57.0	1.77
50302	4.0	60.0	1.500	79	1.98	246	6.15	250	6.25	496	12.40	2.03	50.8	0.95

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Sex: Female Day(s) Relative to Start Date

10 mg/kg	Organ Weights (Monkey)													
	Submand. GL (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GL (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)	Spleen Ratio (%)	Kidney (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50301	44.3	1.64	41.0	3.41	85.3	21.12	0.528	13.55	0.339	71.0	1.78	3.59	0.090	7.17
50302	23.8	0.64	16.0	1.59	39.8	17.78	0.445	15.59	0.390	69.5	1.74	4.81	0.120	9.00

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Sex: Female Day(s) Relative to Start Date

10 mg/kg	Organ Weights (Monkey)													
	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%)	Adrenals (mg)	Adrenals Ratio (^-3%)	Ovary (L) (mg)	Ovary (L)Ratio (^-3%)	Ovary (R) (mg)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50301	0.179	7.16	0.179	14.33	0.358	363	9.08	297	7.43	660	16.50	388	9.70	199
50302	0.225	8.89	0.222	17.89	0.447	367	9.18	267	6.68	634	15.85	456	11.40	172

Sex: Female Day(s) Relative to Start Date

10 mg/kg	Organ Weights (Monkey)				
	Ovary (R)Ratio ([^] -3%)	Ovaries (mg)	Ovaries Ratio ([^] -3%)	Uterus (g)	Uterus Ratio ([^] -3%)
	29	29	29	29	29
50301	4.98	587	14.68	10.48	262.0
50302	4.30	628	15.70	10.24	256.0

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Sex: Female Day(s) Relative to Start Date

30 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%)	Submand. GL (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50401	3.9	56.6	1.451	50	1.28	217	5.56	181	4.64	398	10.21	2.60	66.7	0.93
50402	3.6	73.5	2.042	59	1.64	302	8.39	249	6.92	551	15.31	0.97	26.9	0.91

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Sex: Female Day(s) Relative to Start Date

30 mg/kg	Organ Weights (Monkey)													
	Submand. GL (L)Ratio ([^] -3%)	Submand. GL (R) (g)	Submand. GL (R)Ratio ([^] -3%)	Submand. GLs (g)	Submand. GLs Ratio ([^] -3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)	Spleen Ratio (%)	Kidney (L) (g)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50401	23.8	0.92	23.6	1.85	47.4	19.10	0.490	15.15	0.388	70.6	1.81	3.35	0.086	5.39
50402	25.3	0.85	23.6	1.76	48.9	18.55	0.515	11.88	0.330	68.1	1.89	3.53	0.098	7.11

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Sex: Female Day(s) Relative to Start Date

30 mg/kg	Organ Weights (Monkey)													
	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%)	Adrenals (mg)	Adrenals Ratio (^-3%)	Ovary (L) (mg)	Ovary (L)Ratio (^-3%)	Ovary (R) (mg)
	29	29	29	29	29	29	29	29	29	29	29	29	29	29
50401	0.138	5.58	0.143	10.97	0.281	310	7.95	225	5.77	535	13.72	301	7.72	140
50402	0.198	7.26	0.202	14.37	0.399	291	8.08	235	6.53	526	14.61	302	8.39	153

Sex: Female Day(s) Relative to Start Date

30 mg/kg	Organ Weights (Monkey)				
	Ovary (R)Ratio (^3%)	Ovaries (mg)	Ovaries Ratio (^3%)	Uterus (g)	Uterus Ratio (^3%)
	29	29	29	29	29
50401	3.59	441	11.31	11.87	304.4
50402	4.25	455	12.64	5.39	149.7

Animal: 10101 Sex: Male

Dose: 0 mg/kg
Removal Reason: Scheduled Sacrifice
Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Heart : Cell infiltration; inflammatory, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Aorta; Kidney; Urinary Bladder; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 10102 Sex: Male

Dose: 0 mg/kg
Removal Reason: Scheduled Sacrifice
Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Duodenum : Pigment deposition; macrophage, brown, minimal
Liver : Cell infiltration; inflammatory, focal, minimal
Kidney : Cell infiltration; lymphocyte, focal, minimal
Prostate : Cell infiltration; inflammatory, focal, minimal
Thyroid : Cell infiltration; lymphocyte, focal, minimal
Thyroid : Cell infiltration; macrophage, follicle, minimal
Eyeball : Cell infiltration; mononuclear cell, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Jejunum; Ileum; Cecum; Colon; Rectum; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Urinary Bladder; Testis; Epididymis; Seminal Vesicle; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 50101 Sex: Female

Dose: 0 mg/kg
Removal Reason: Scheduled Sacrifice
Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal
Parotid Gland : Cell infiltration; lymphocyte, focal, minimal

Histo Pathology Observations [Correlation] (Continued):

Lacrimal Gland : Cell infiltration; lymphocyte, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Mesenteric Lymph Node; Heart; Aorta; Kidney; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 50102

Sex: Female

Dose: 0 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Stomach : Cell infiltration; inflammatory, lamina propria, diffuse, minimal

Mesenteric Lymph Node : Increase; pigmentophagy, minimal

Heart : Cell infiltration; inflammatory, focal, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Liver; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Lungs (And Bronchus); Thymus; Spleen; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Aorta; Kidney; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb

Animal: 10201

Sex: Male

Dose: 1 mg/kg

Removal Reason: Scheduled Sacrifice

Study Day (Week) of Death: 29 (5)

Gross Pathology Observations [Correlation]:

Necropsy Findings : Absent

Histo Pathology Observations [Correlation]:

Liver : Cell infiltration; inflammatory, focal, minimal

Parotid Gland : Cell infiltration; lymphocyte, focal, minimal

Spleen : Pigment deposition; brown, red pulp, minimal

Bone Marrow (Femur) : Pigment deposition; brown, minimal

Mesenteric Lymph Node : Increase; pigmentophagy, minimal

Kidney : Cell infiltration; lymphocyte, focal, minimal

Urinary Bladder : Cell infiltration; lymphocyte, focal, minimal

Prostate : Cell infiltration; inflammatory, focal, minimal

Pituitary : Cyst

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Duodenum; Jejunum; Ileum; Cecum; Colon; Rectum; Gallbladder; Pancreas; Submandibular Gland; Sublingual Gland; Trachea; Lungs (And Bronchus); Thymus; Bone Marrow (Sternum); Mandibular Lymph Node; Heart; Aorta; Testis; Epididymis; Seminal Vesicle; Mammary Gland; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Lacrimal Gland; Femoral Muscle; Femur; Sternum; Skin; Administered Site, Right Forelimb; Administered Site, Right Hindlimb; Administered Site, Left Forelimb; Administered Site, Left Hindlimb