

Animal: 10407		Sex: Male
Material: P092	Dose: 80 mg/kg	
	Removal Reason: Scheduled Sacrifice	
	Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal
 Duodenum : Accumulation, Foam Cell; lamina propria, mild
 Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal
 Jejunum : Vacuolation, Mucosal Epithelium; minimal
 Jejunum : Accumulation, Foam Cell; lamina propria, mild
 Jejunum : Cell Infiltration, Neutrophil; lamina propria, minimal
 Ileum : Accumulation, Foam Cell; lamina propria, mild
 Ileum : Cell Infiltration, Neutrophil; lamina propria, mild
 Ileum : Hyperplasia, Mucosal Epithelium; minimal
 Cecum : Vacuolation, Mucosal Epithelium; minimal
 Colon : Vacuolation, Mucosal Epithelium; minimal
 Rectum : Vacuolation, Mucosal Epithelium; minimal
 Liver : Vacuolation, Hepatocyte; diffuse, mild
 Liver : Vacuolation, Bile Ductal Epithelium; minimal
 Liver : Vacuolation, Kupffer Cell; minimal
 Liver : Cell Infiltration, Inflammatory; focal, minimal
 Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild
 Thymus : Increase, Karyorrhexis, Lymphocyte; minimal
 Spleen : Accumulation, Foamy Macrophage; mild
 Spleen : Vacuolation; macrophage, marginal zone, minimal
 Spleen : Cell Infiltration, Neutrophil; minimal
 Bone Marrow (Femur) : Increase, Hematopoietic Cell, Granulocytic; minimal
 Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal
 Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal
 Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild
 Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal
 Kidney : Vacuolation; distal tubular epithelium, minimal
 Kidney : Vacuolation; epithelial cell, glomerulus, minimal
 Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Heart; Aorta; Urinary Bladder; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 10408

Sex: Male

Material: P092

Dose: 80 mg/kg

Removal Reason: Scheduled Sacrifice

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

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Regeneration, Mucosal Epithelium; mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, minimal

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; minimal

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Kidney : Basophilic Tubule; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Heart; Aorta; Urinary Bladder; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 10409		Sex: Male
Material: P092	Dose: 80 mg/kg	
	Removal Reason: Scheduled Sacrifice	
	Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Duodenum : Distention

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Heart; Aorta; Urinary Bladder; Testis; Epididymis; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	10410		Sex: Male
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present
 Duodenum : Distention
 Jejunum : Distention
 Ileum : Distention
 Testis : Small; bilateral (TGL)
 Epididymis : Small; bilateral (TGL)

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal
 Duodenum : Accumulation, Foam Cell; lamina propria, mild
 Jejunum : Vacuolation, Mucosal Epithelium; minimal
 Jejunum : Accumulation, Foam Cell; lamina propria, moderate
 Jejunum : Cell Infiltration, Neutrophil; lamina propria, minimal
 Ileum : Vacuolation, Mucosal Epithelium; minimal
 Ileum : Accumulation, Foam Cell; lamina propria, mild
 Cecum : Vacuolation, Mucosal Epithelium; minimal
 Rectum : Vacuolation, Mucosal Epithelium; minimal
 Liver : Vacuolation, Hepatocyte; diffuse, minimal
 Liver : Vacuolation, Bile Ductal Epithelium; minimal
 Liver : Vacuolation, Kupffer Cell; minimal
 Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild
 Lungs (And Bronchus) : Osseous Metaplasia; minimal
 Spleen : Accumulation, Foamy Macrophage; moderate
 Spleen : Vacuolation; macrophage, marginal zone, minimal
 Spleen : Cell Infiltration, Neutrophil; minimal
 Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal
 Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal
 Heart : Cell Infiltration, Inflammatory; focal, minimal
 Kidney : Vacuolation; distal tubular epithelium, minimal
 Kidney : Vacuolation; proximal tubular epithelium, minimal
 Kidney : Basophilic Tubule; minimal
 Testis : Atrophy, Seminiferous Tubule; bilateral, diffuse, moderate [Testis : Small; bilateral (G)]
 Testis : Hyperplasia, Interstitial Cell; bilateral, minimal [Testis : Small; bilateral (G)]
 Epididymis : Decrease, Sperm, Duct; bilateral, moderate [Epididymis : Small; bilateral (G)]

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Aorta; Urinary Bladder; Prostate; Seminal Vesicle; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 50401

Sex: Female

Material: P092

Dose: 80 mg/kg

Removal Reason: Scheduled Sacrifice

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

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Duodenum : Distention

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Bone Marrow (Femur) : Increase, Hematopoietic Cell, Granulocytic; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Kidney : Basophilic Tubule; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus;

Mandibular Lymph Node; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid;

Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50402		Sex: Female
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Regeneration, Mucosal Epithelium; mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Colon : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, minimal

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Mandibular Lymph Node; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50403		Sex:	Female
Material:	P092	Dose:	80 mg/kg	
		Removal Reason:	Scheduled Sacrifice	
		Study Day (Week) of Death:	29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, mild

Ileum : Regeneration, Mucosal Epithelium; minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, minimal

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; moderate

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Spleen : Necrosis; macrophage, minimal

Bone Marrow (Femur) : Increase, Hematopoietic Cell, Granulocytic; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50404		Sex: Female
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Ileum : Distention

Liver : Whitish Patch; right lateral lobe, many (TGL)

Liver : Enlargement; right lateral lobe (TGL)

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, moderate

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild [Liver : Enlargement; right lateral lobe (G)]

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Liver : Necrosis, Hepatocyte; focal, mild [Liver : Whitish Patch; right lateral lobe, many (G)]

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Lungs (And Bronchus) : Osseous Metaplasia; minimal

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Kidney : Basophilic Tubule; minimal

Thyroid : Ultimobranchial Remnant; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 50405

Sex: Female

Material: P092

Dose: 80 mg/kg

Removal Reason: Scheduled Sacrifice

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

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Duodenum : Distention

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Colon : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Liver : Cell Infiltration, Inflammatory; focal, minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; moderate

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Bone Marrow (Femur) : Increase, Hematopoietic Cell, Granulocytic; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Cell Infiltration, Neutrophil; sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Thyroid : Ultimobranchial Remnant; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Heart; Aorta;
 Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic
 Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 50406

Sex: Female

Material: P092

Dose: 80 mg/kg

Removal Reason: Scheduled Sacrifice

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

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, moderate

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Lungs (And Bronchus) : Mineralization, Arterial Wall; minimal

Thymus : Increase, Karyorrhexis, Lymphocyte; minimal

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Bone Marrow (Femur); Bone Marrow (Sternum); Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50407		Sex: Female
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Mesenteric Lymph Node : Enlargement (TGL)

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, moderate

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, minimal

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Bone Marrow (Femur) : Increase, Hematopoietic Cell, Granulocytic; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild [Mesenteric Lymph Node : Enlargement (G)]

Mesenteric Lymph Node : Necrosis; macrophage, sinus, mild

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50408		Sex: Female
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Histo Pathology Observations [Correlation]:

Stomach : Single Cell Necrosis, Mucosal Epithelium; glandular stomach, minimal

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, moderate

Jejunum : Cell Infiltration, Neutrophil; lamina propria, minimal

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Cell Infiltration, Neutrophil; sinus, minimal

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Thyroid : Ultimobranchial Remnant; minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Bone Marrow (Sternum); Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal: 50409

Sex: Female

Material: P092

Dose: 80 mg/kg

Removal Reason: Scheduled Sacrifice

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

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Liver : Whitish Patch; right lateral lobe, one (TGL)

Histo Pathology Observations [Correlation]:

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Regeneration, Mucosal Epithelium; mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Liver : Necrosis, Hepatocyte; focal, mild [Liver : Whitish Patch; right lateral lobe, one (G)]

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Thymus : Increase, Karyorrhexis, Lymphocyte; minimal

Spleen : Accumulation, Foamy Macrophage; mild

Spleen : Vacuolation; macrophage, marginal zone, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild

Mesenteric Lymph Node : Cell Infiltration, Neutrophil; sinus, minimal

Mesenteric Lymph Node : Necrosis; macrophage, sinus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Bone Marrow (Femur); Bone Marrow (Sternum); Mandibular Lymph Node; Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions || (G): Gross Pathology]

Animal:	50410		Sex: Female
Material:	P092	Dose: 80 mg/kg	
		Removal Reason: Scheduled Sacrifice	
		Study Day (Week) of Death: 29 (5)	

Gross Pathology Observations [Correlation]:

Necropsy Findings : Present

Jejunum : Distention

Ileum : Distention

Mesenteric Lymph Node : Enlargement (TGL)

Histo Pathology Observations [Correlation]:

Duodenum : Vacuolation, Mucosal Epithelium; minimal

Duodenum : Accumulation, Foam Cell; lamina propria, mild

Duodenum : Cell Infiltration, Neutrophil; lamina propria, minimal

Jejunum : Vacuolation, Mucosal Epithelium; minimal

Jejunum : Accumulation, Foam Cell; lamina propria, mild

Jejunum : Cell Infiltration, Neutrophil; lamina propria, mild

Jejunum : Regeneration, Mucosal Epithelium; mild

Ileum : Vacuolation, Mucosal Epithelium; minimal

Ileum : Accumulation, Foam Cell; lamina propria, mild

Ileum : Cell Infiltration, Neutrophil; lamina propria, mild

Ileum : Regeneration, Mucosal Epithelium; minimal

Cecum : Vacuolation, Mucosal Epithelium; minimal

Rectum : Vacuolation, Mucosal Epithelium; minimal

Liver : Vacuolation, Hepatocyte; diffuse, mild

Liver : Vacuolation, Bile Ductal Epithelium; minimal

Liver : Vacuolation, Kupffer Cell; minimal

Lungs (And Bronchus) : Accumulation, Foam Cell, Alveolus; mild

Spleen : Accumulation, Foamy Macrophage; moderate

Spleen : Vacuolation; macrophage, marginal zone, minimal

Spleen : Cell Infiltration, Neutrophil; minimal

Bone Marrow (Sternum) : Increase, Hematopoietic Cell, Granulocytic; minimal

Mandibular Lymph Node : Accumulation, Foamy Macrophage; sinus, minimal

Mesenteric Lymph Node : Accumulation, Foamy Macrophage; sinus, mild [Mesenteric Lymph Node : Enlargement (G)]

Mesenteric Lymph Node : Cell Infiltration, Neutrophil; sinus, minimal

Mesenteric Lymph Node : Necrosis; macrophage, sinus, mild

Kidney : Vacuolation; distal tubular epithelium, minimal

Kidney : Vacuolation; epithelial cell, glomerulus, minimal

Kidney : Vacuolation; proximal tubular epithelium, minimal

Histo Pathology - The following Tissues were Within Normal Limits:

Tongue; Esophagus; Stomach; Colon; Pancreas; Submandibular Gland; Sublingual Gland; Parotid Gland; Trachea; Thymus; Bone Marrow (Femur); Heart; Aorta; Urinary Bladder; Ovary; Uterus; Vagina; Mammary Gland; Pituitary; Thyroid; Parathyroid; Adrenal; Brain; Spinal Cord; Optic Nerve; Sciatic Nerve; Eyeball; Harderian Gland; Femoral Muscle; Femur; Sternum; Knee Joint; Skin

General Footnote: [(TGL): Trackable Gross Lesions] (G): Gross Pathology]

Appendix 11 Calibration standards on each analytical day

B120720

Date	Calibration curve			Back ground (% of LLOQ)			QC sample			
	Concentration (ng/ml)		%RE	Sample	Peak area		Concentration (ng/mL)			
	Nominal	Measured			P092	IS	Nominal	No.	Measured	%RE
2012/12/17	5	5.47	9.4	Blank	0	12346	10	1	10.9	9.0
	10	10.3	3.0		(0.0)	(4.8)		2	11.3	13.0
	20	19.3	-3.5	Zero	0	263223	50	1	54.8	9.6
	50	51.1	2.2		(0.0)	--		2	53.4	6.8
	100	92.5	-7.5	LLOQ	1793	258916	800	1	799	-0.1
	200	191	-4.5					2	865	8.1
	500	493	-1.4							
	1000	1020	2.0							
2012/12/18	5	5.76	15.2	Blank	0	7990	10	1	9.53	-4.7
	10	9.72	-2.8		(0.0)	(3.6)		2	10.2	2.0
	20	19.2	-4.0	Zero	0	230026	50	1	45.4	-9.2
	50	50.8	1.6		(0.0)	--		2	47.2	-5.6
	100	102	2.0	LLOQ	1894	224414	800	1	753	-5.9
	200	181	-9.5					2	684	-14.5
	500	458	-8.4							
	1000	1060	6.0							
2013/1/9	5	5.40	8.0	Blank	0	2539	10	1	11.8	18.0
	10	11.1	11.0		(0.0)	(1.3)		2	10.4	4.0
	20	20.7	3.5	Zero	0	201401	50	1	53.6	7.2
	50	43.7	-12.6		(0.0)	--		2	48.4	-3.2
	100	98.6	-1.4	LLOQ	6704	191330	800	1	425	-46.9
	200	179	-10.5					2	680	-15.0
	500	491	-1.8							
	1000	1040	4.0							
2013/1/10	5	4.74	-5.2	Blank	0	1131	10	1	12.6	26.0
	10*	13.1	--		(0.0)	(0.6)		2	9.19	-8.1
	20	18.0	-10.0	Zero	0	228271	50	1	53.3	6.6
	50	50.6	1.2		(0.0)	--		2	52.0	4.0
	100*	121	--	LLOQ	3526	184928	800	1	881	10.1
	200	227	13.5					2	873	9.1
	500	529	5.8							
	1000	946	-5.4							

RE: Relative error, LLOQ: Lower limit of quantification

%RE = (measured value - nominal value)/nominal value × 100

The value in parenthesis denotes peak area ratio (%) of back ground peak area to that in LLOQ.

--: Not applicable

*: Since the accuracy did not satisfy the criterion, the calibration curve was constructed again using the results except for these concentrations.

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date									
					1 Before dosing	1 Time 10	2 Before dosing	2 Time 10	3 Before dosing	3 Time 10	4 Before dosing	4 Time 10	5 Before dosing	
5	m	20101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 5 - 0 mg/kg Group 6 - 5 mg/kg Group 7 - 20 mg/kg Group 8 - 80 mg/kg

Day 1 to 23: Time 10, About 2 hours after dosing

Day 24 to 28: Time 10 Just after dosing; Time 20, About 2 hours after dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	5		6		7		8		9	
					Time 10	Before dosing								
5	m	20101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 5 - 0 mg/kg Group 6 - 5 mg/kg Group 7 - 20 mg/kg Group 8 - 80 mg/kg

Day 1 to 23: Time 10, About 2 hours after dosing

Day 24 to 28: Time 10 Just after dosing; Time 20, About 2 hours after dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date									
					10 Before dosing	10 Time 10	11 Before dosing	11 Time 10	12 Before dosing	12 Time 10	13 Before dosing	13 Time 10	14 Before dosing	
5	m	20101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 5 - 0 mg/kg Group 6 - 5 mg/kg Group 7 - 20 mg/kg Group 8 - 80 mg/kg

Day 1 to 23: Time 10, About 2 hours after dosing

Day 24 to 28: Time 10 Just after dosing; Time 20, About 2 hours after dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	14		15		16		17		18	
					Time 10	Before dosing								
5	m	20101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X
		20103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 5 - 0 mg/kg Group 6 - 5 mg/kg Group 7 - 20 mg/kg Group 8 - 80 mg/kg

Day 1 to 23: Time 10, About 2 hours after dosing

Day 24 to 28: Time 10 Just after dosing; Time 20, About 2 hours after dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date											
					19 Before dosing	19 Time 10	20 Before dosing	20 Time 10	21 Before dosing	21 Time 10	22 Before dosing	22 Time 10	23 Before dosing			
5	m	20101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X		
		20102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X		
		20103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X		

Severity Codes: X = Present

Group 5 - 0 mg/kg Group 6 - 5 mg/kg Group 7 - 20 mg/kg Group 8 - 80 mg/kg

Day 1 to 23: Time 10, About 2 hours after dosing

Day 24 to 28: Time 10 Just after dosing; Time 20, About 2 hours after dosing