

TRADE SECRET

Study Title

H-24516: Subchronic Toxicity
90-Day Gavage Study in Rats
with One-Generation Reproduction Evaluations

Volume 4 of 5

Laboratory Project ID: DuPont-5386

TEST GUIDELINES: U.S. EPA Health Effects Test Guidelines
OPPTS 870.3100 (1998)

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643330

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Macroscopic Abnormality Observed :

NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643336 Unscheduled Sacrifice

Duration of dosing-days: 105

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

KIDNEYS :

CALCULUS\CALCULI, BILATERAL, severe.

URINARY BLADDER :

CALCULUS\CALCULI, severe.

No Macroscopic Abnormality Observed :

LIVER, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN,
SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

MINERALIZATION, mild.

NECROSIS, TUBULAR, mild.

HYPERPLASIA, TRANSITIONAL CELL, moderate.

INFLAMMATION, ACUTE, mild.

THYMUS :

ATROPHY, mild.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643336 Continued from previous page

Histopathology :

URINARY BLADDER :

HYPERPLASIA, SIMPLE, TRANSITIONAL CELL, moderate.
INFLAMMATION, SUBACUTE/CHRONIC, mild.
HEMORRHAGE, mild.

BONE MARROW :

HYPERPLASIA, GRANULOCYTIC, mild.

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL
CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM,
COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS,
MANDIBULAR LYMPH NODE, ADRENAL GLANDS, SCIATIC NERVE,
PITUITARY GLAND, THYROID GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643354

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643354 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE, MANDIBLE

643361

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643361 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

PARATHYROID GLANDS :

NOT PRESENT.

No Macroscopic Abnormality Observed :

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643362

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

NECROSIS, FOCAL, minimal.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

HEART :

CARDIOMYOPATHY, minimal.

643362 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643362 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

LUNGS, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL CORD,
STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON,
RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR
LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE,
PITUITARY GLAND, THYROID GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

643374

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643374 Continued from previous page

Histopathology :

LIVER :

FATTY CHANGE, MEDIAN CLEFT, mild.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

No Microscopic Abnormality Observed :
KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

643377

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

PITUITARY GLAND :

LARGE.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
643377	Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :
NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643383

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, mild.

NOSE :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL, mild.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643384

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :
NOSE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643387

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643398

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
FATTY CHANGE, MEDIAN CLEFT, mild.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

HEART :

CARDIOMYOPATHY, minimal.

PARATHYROID GLANDS :

NOT PRESENT.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643398 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

LUNGS, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL CORD,
STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON,
RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR
LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE,
PITUITARY GLAND, THYROID GLAND, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE, MANDIBLE

643402

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643402 Continued from previous page

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.No Microscopic Abnormality Observed :
NOSE

643405

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
NECROSIS, FOCAL, minimal.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643405 Continued from previous page

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.No Microscopic Abnormality Observed :
KIDNEYS, NOSE, MANDIBLE

643406

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

643406 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643406 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

643415

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

PITUITARY GLAND :
LARGE.

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, THYROID GLAND,

643415 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643415 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE, MANDIBLE

Histopathology :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
PITUITARY GLAND :
HYPERPLASIA, DIFFUSE, mild.
NOSE :
SQUAMOUS HYPERPLASIA, NASOLACRIMAL DUCT, mild.

No Microscopic Abnormality Observed :
LIVER, THYROID GLAND, MANDIBLE

643425

Terminal Sacrifice
Killed on Day : 125
Exposure Group : ONE-MONTH RECOVERY
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
Continued on the next page

643425

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643425 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

FATTY CHANGE, MEDIAN CLEFT, minimal.

KIDNEYS :

HYDRONEPHROSIS, BILATERAL, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Macroscopic Abnormality Observed :

NOSE, MANDIBLE

643426

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643426 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643426 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.

No Macroscopic Abnormality Observed :
NOSE, MANDIBLE

643436

Terminal Sacrifice
Killed on Day : 93
Exposure Group : 90-DAY EXPOSURE
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
643436 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
643436	Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
KIDNEYS :
CYST, minimal.
HEART :
CARDIOMYOPATHY, minimal.

No Microscopic Abnormality Observed :
LUNGS, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL CORD,
STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON,
RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR
LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE,
PITUITARY GLAND, THYROID GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643448

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

No Macroscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643453

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
CYST, minimal.

No Microscopic Abnormality Observed :

THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643463

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

LUNGS :

THROMBUS, minimal.

EYE(S) WITH OPTIC NERVE :

OPTIC NERVE NOT PRESENT.

No Macroscopic Abnormality Observed :

KIDNEYS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN,
SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,

643463 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643463 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE, MANDIBLE

643465

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.

643465 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643465 Continued from previous page

Histopathology :

NOSE :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL, mild.

643477

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

643477 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643477 Continued from previous page

Histopathology :

PARATHYROID GLANDS :

NOT PRESENT.

EYE(S) WITH OPTIC NERVE :

OPTIC NERVE NOT PRESENT.

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL
CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM,
COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS,
MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC
NERVE, PITUITARY GLAND, THYROID GLAND, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE, MANDIBLE

643484

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643484 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643484 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.
NOSE :
INFLAMMATION, SUBACUTE/CHRONIC, mild.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL, mild.

643486

Terminal Sacrifice
Killed on Day : 93
Exposure Group : 90-DAY EXPOSURE
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643486 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : II - 0 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643486 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

MESENTERIC LYMPH NODE :

NOT PRESENT.

PARATHYROID GLANDS :

NOT PRESENT.

No Microscopic Abnormality Observed :

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, SALIVARY GLANDS, MANDIBULAR
LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE,
PITUITARY GLAND, THYROID GLAND, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643321

Unscheduled Sacrifice

Duration of dosing-days: 29

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

KIDNEYS :

DILATATION, BILATERAL, PELVIS, moderate.

DISCOLORATION, TAN, BILATERAL, GRANULAR .

URINARY BLADDER :

DILATATION, severe.

CALCULUS\CALCULI, 7MM DIA.

No. Macroscopic Abnormality Observed :

LIVER, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN,
SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

KIDNEYS :

HYDRONEPHROSIS, BILATERAL, mild.

INFLAMMATION, ACUTE, moderate.

HYPERPLASIA, TRANSITIONAL CELL, mild.

NECROSIS, TUBULAR, moderate.

HEART :

CARDIOMYOPATHY, minimal.

643321 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643321 Continued from previous page

Histopathology :

SPLEEN :
 DEPLETION, LYMPHOID, moderate.
 THYMUS :
 ATROPHY, moderate.
 URINARY BLADDER :
 HYPERPLASIA, SIMPLE, TRANSITIONAL CELL, moderate.
 BONE MARROW :
 ATROPHY, mild.
 MANDIBLE :
 NOT PRESENT.

No Microscopic Abnormality Observed :
 LIVER, LUNGS, SKELETAL MUSCLE, AORTA, BRAIN, SPINAL CORD,
 STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON,
 RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR
 LYMPH NODE, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
 THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
 PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
 GLAND (FEMALE), OVARIES, UTERUS, FEMUR/KNEE JOINT, STERNUM,
 NOSE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643324

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643364

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

No Microscopic Abnormality Observed :

THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643379

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, minimal.

643380

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643380 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643380 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
 INFLAMMATION, SUBACUTE/CHRONIC, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :
KIDNEYS, NOSE, MANDIBLE

643389

Terminal Sacrifice
Killed on Day : 93
Exposure Group : 90-DAY EXPOSURE
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643389 Continued on the next page

90-Day Gavage Study in Rats with One-Generation Reproduction Evaluations

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643389 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :
INFLAMMATION, SUBACUTE/CHRONIC, mild.
FRACTURE/CALLUS, TOOTH.

No Macroscopic Abnormality Observed :
KIDNEYS, MANDIBLE

643390

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643390 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643390 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

No Microscopic Abnormality Observed :
KIDNEYS, THYROID GLAND, NOSE, MANDIBLE

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643391 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643391 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.

643396

Terminal Sacrifice
Killed on Day : 93
Exposure Group : 90-DAY EXPOSURE
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643396 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643396 Continued from previous page

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

No Microscopic Abnormality Observed :

THYROID GLAND, NOSE, MANDIBLE

643410

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643410 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643410 Continued from previous page

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, NOSE, MANDIBLE

643433

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643433 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643433 Continued from previous page

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, NOSE, MANDIBLE

643437

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

643437 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643437 Continued from previous page

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.

643458

Terminal Sacrifice
Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
FATTY CHANGE, MEDIAN CLEFT, minimal.

THYROID GLAND :
ALTERATION, COLLOID, minimal.

643458 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : IV - 25 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643458 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
KIDNEYS, NOSE, MANDIBLE

643483

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, moderate.

90-Day Gavage Study in Rats with One-Generation Reproduction Evaluations

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643322 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

NOSE : DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, THYROID GLAND, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643323 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

No Microscopic Abnormality Observed :

THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643360

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL, mild.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643366 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, moderate.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643367

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643373

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, mild.

No Microscopic Abnormality Observed :
NOSE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643381

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.

NOSE :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL,
minimal.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643382

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

No Microscopic Abnormality Observed :

THYROID GLAND, NOSE

643392

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

LUNGS :

DISCOLORATION, DARK.

643392 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643392 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

No Microscopic Abnormality Observed :

LUNGS, THYROID GLAND, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643409 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643412

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

NOSE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643461

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643462

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643472

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VI - 100 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643489

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
NECROSIS, FOCAL, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643329

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, mild.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643332

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, mild.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

UTERUS :

DILATATION, LUMEN, mild.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

DEGENERATION, AMELOBLASTS, mild.

643332 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

Animal Ref Microscopic & Macroscopic Findings

643332 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, BONE
MARROW

643340

Found Dead

Duration of dosing-days: 69

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

ADRENAL GLANDS :

LARGE, BILATERAL, moderate.

WHOLE BODY :

Autolysis: tissues taken, severe.

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,

643340 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643340 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE

Histopathology :

SPLEEN :

DEPLETION, LYMPHOID, mild.

JEJUNUM :

AUTOLYSIS: NECROPSY AND HISTOLOGY PERFORMED, moderate.

THYMUS :

ATROPHY, severe.

PARATHYROID GLANDS :

NOT PRESENT.

EYE(S) WITH OPTIC NERVE :

AUTOLYSIS: NECROPSY AND HISTOLOGY PERFORMED, mild.

NOSE :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

NOT PRESENT.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings
-----643340 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND, TRACHEA,
ESOPHAGUS, PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN,
MAMMARY GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW

643341

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643341 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643341 Continued from previous page

Histopathology :

LIVER :
 HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, mild.
SPLEEN :
 NOT PRESENT.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
UTERUS :
 DILATATION, LUMEN, minimal.
NOSE :
 DEGENERATION, AMELOBLASTS, mild.
MANDIBLE :
 DEGENERATION, AMELOBLASTS, mild.

No Microscopic Abnormality Observed :
KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, AORTA, BRAIN,
SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, BONE
MARROW

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643345 Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

No Microscopic Abnormality Observed :

KIDNEYS, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643347

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, THYROID GLAND, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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643351	Terminal Sacrifice
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Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

LIVER, KIDNEYS, NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643356

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, moderate.

NOSE :

INFLAMMATION, SUBACUTE/CHRONIC, mild.
DEGENERATION, AMELOBLASTS, minimal.

HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL, mild.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643358 Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

No Microscopic Abnormality Observed :

MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643359 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, minimal.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.
ALTERATION, COLLOID, minimal.

PARATHYROID GLANDS :

NOT PRESENT.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

DEGENERATION, AMELOBLASTS, mild.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643359 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL
GLANDS, SCIATIC NERVE, PITUITARY GLAND, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW

643368

Accidentally Killed

Duration of dosing-days: 53

Exposure Group : REPRODUCTION

Animal is signed off from necropsy

Gross Pathology :

ESOPHAGUS :

PUNCTURE, GAVAGE ERROR.

SKIN :

STAIN.

RED, PERINEUM.

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643368 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643368 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, MAMMARY GLAND (FEMALE), OVARIES,
UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

KIDNEYS :

AUTOLYSIS: NECROPSY AND HISTOLOGY PERFORMED, mild.

SPLEEN :

DEPLETION, LYMPHOID, mild.

JEJUNUM :

AUTOLYSIS: NECROPSY AND HISTOLOGY PERFORMED, moderate.

THYMUS :

ATROPHY, severe.

ESOPHAGUS :

INFLAMMATION, SUBACUTE/CHRONIC, severe.

BONE MARROW :

HYPERPLASIA, GRANULOCYTIC, severe.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

NOT PRESENT.

643368 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643368 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE,
SALIVARY GLANDS, MANDIBULAR LYMPH NODE, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND,
PARATHYROID GLANDS, TRACHEA, PHARYNX/LARYNX, EYE(S) WITH
OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE), OVARIES, UTERUS,
URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM

643370

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

643370 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643370 Continued from previous page

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, mild.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

INFARCT, minimal.
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
MESENTERIC LYMPH NODE :
NOT PRESENT.

PARATHYROID GLANDS :

NOT PRESENT.

EYE(S) WITH OPTIC NERVE :

OPTIC NERVE NOT PRESENT.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

DEGENERATION, AMELOBLASTS, mild.

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL
CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM,
COLON, RECTUM, SALIVARY GLANDS, MANDIBULAR LYMPH NODE,
THYMUS, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643388

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, mild.

NOSE :

HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL,
minimal.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643404

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, mild.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, moderate.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

643404 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643404 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, BONE MARROW, MANDIBLE

643408

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND, THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, NOSE

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643408 Continued from previous page

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, minimal.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.
ALTERATION, COLLOID, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

NOT PRESENT.

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL
CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM,
COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY GLANDS,
MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS, SCIATIC
NERVE, PITUITARY GLAND, PARATHYROID GLANDS, TRACHEA,
ESOPHAGUS, PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN,
MAMMARY GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643423

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :

NOSE, MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643435

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, mild.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

PANCREAS :

ATROPHY, minimal.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.
ALTERATION, COLLOID, minimal.

UTERUS :

DILATATION, LUMEN, minimal.

URINARY BLADDER :

NOT PRESENT.

643435 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643435 Continued from previous page

Histopathology :

NOSE :
DEGENERATION, AMELOBLASTS, mild.
MANDIBLE :
DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :
KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, PARATHYROID GLANDS,
TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, FEMUR/KNEE JOINT, STERNUM, BONE MARROW

643441

Terminal Sacrifice
Killed on Day : 125
Exposure Group : ONE-MONTH RECOVERY
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643441 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643441 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
FATTY CHANGE, MEDIAN CLEFT, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
NOSE :
DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :
MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643444

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, minimal.
NECROSIS, FOCAL, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

NOSE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643446 Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, minimal.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

PANCREAS :

ATROPHY, minimal.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.
ALTERATION, COLLOID, mild.

PARATHYROID GLANDS :

NOT PRESENT.

EYE(S) WITH OPTIC NERVE :

OPTIC NERVE NOT PRESENT.

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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643446 Continued from previous page

Histopathology :

NOSE : DEGENERATION, AMELOBLASTS, mild.

MANDIBLE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA,
BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM,
CECUM, COLON, RECTUM, MESENTERIC LYMPH NODE, SALIVARY
GLANDS, MANDIBULAR LYMPH NODE, THYMUS, ADRENAL GLANDS,
SCIATIC NERVE, PITUITARY GLAND, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW

643450

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643450 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643450 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :

THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, mild.

NOSE :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
HYPERPLASIA/SQUAMOUS METAPLASIA, TRANSITIONAL CELL,
minimal.

643456

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643456 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643456 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
NOSE :
DEGENERATION, AMELOBLASTS, mild.
INFLAMMATION, SUBACUTE/CHRONIC, NASOLACRIMAL DUCT, mild.

No Microscopic Abnormality Observed :
MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643466

Terminal Sacrifice

Killed on Day : 93

Exposure Group : 90-DAY EXPOSURE

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :

HYPERTROPHY, HEPATOCYTE, CENTRILOBULAR, minimal.
INFLAMMATION, SUBACUTE/CHRONIC, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

MESENTERIC LYMPH NODE :

NOT PRESENT.

THYROID GLAND :

HYPERTROPHY, FOLLICULAR, minimal.
ALTERATION, COLLOID, mild.

EYE(S) WITH OPTIC NERVE :

OPTIC NERVE NOT PRESENT.

643466 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643466 Continued from previous page

Histopathology :

NOSE : DEGENERATION, AMELOBLASTS, mild.
MANDIBLE :

DEGENERATION, AMELOBLASTS, minimal.

No Microscopic Abnormality Observed :

LUNGS, HEART, SKELETAL MUSCLE, SPLEEN, AORTA, BRAIN, SPINAL
CORD, STOMACH, DUODENUM, JEJUNUM, ILEUM, PANCREAS, CECUM,
COLON, RECTUM, SALIVARY GLANDS, MANDIBULAR LYMPH NODE,
THYMUS, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
PARATHYROID GLANDS, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX,
EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE),
OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW

643474

Terminal Sacrifice

Killed on Day : 125

Exposure Group : ONE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,

643474 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643474 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.

No Microscopic Abnormality Observed :
KIDNEYS, NOSE, MANDIBLE

643481

Terminal Sacrifice
Killed on Day : 125
Exposure Group : ONE-MONTH RECOVERY
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
643481 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643481 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE, MANDIBLE

Histopathology :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, moderate.
NOSE :
DEGENERATION, AMELOBLASTS, mild.

No Microscopic Abnormality Observed :
MANDIBLE

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 250 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

643487

Terminal Sacrifice

Killed on Day : 181

Exposure Group : THREE-MONTH RECOVERY

Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, STOMACH, DUODENUM, JEJUNUM,
ILEUM, PANCREAS, CECUM, COLON, RECTUM, MESENTERIC LYMPH
NODE, SALIVARY GLANDS, MANDIBULAR LYMPH NODE, THYMUS,
ADRENAL GLANDS, SCIATIC NERVE, PITUITARY GLAND,
THYROID GLAND, PARATHYROID GLANDS, TRACHEA, ESOPHAGUS,
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

THYROID GLAND :

ALTERATION, COLLOID, mild.

No Microscopic Abnormality Observed :

NOSE

APPENDIX O
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL BODY WEIGHTS OF P₁ MALE RATS

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS OF P₁ MALE RATS

EXPLANATORY NOTES

Notes:

Test Days 75 – 89 = Cohabitation period

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: I-0

DOSE: 0 MG/KG/DAY

TEST DAYS:	78	85	92	99	106
ANIMAL NUMBER					
643239	602.8	614.2	627.7	625.4	648.8
643270	514.2	539.7	552.6	562.6	569.4
643148	515.9	520.4	539.2	556.3	569.5
643284	624.5	644.1	647.5	664.9	681.1
643229	465.5	480.7	484.6	506.3	513.3
643196	441.0	454.9	465.7	482.6	493.0
643176	522.9	533.6	556.8	569.3	575.8
643218	564.4	575.4	595.5	608.0	626.0
643207	507.3	522.7	528.4	538.7	541.9
643280	560.0	578.7	586.8	598.1	614.9
643271	635.1	636.5	649.3	669.5	676.4
643211	525.9	540.9	551.5	570.5	582.0
643163	651.7	675.1	692.9	704.6	716.0
643197	565.1	580.0	596.4	604.4	617.4
643242	587.4	591.1	617.3	627.2	637.9
643251	524.9	539.2	557.9	563.1	577.1
643155	582.0	597.9	601.1	613.8	631.2
643147	562.8	574.2	587.9	600.1	605.8
643276	677.2	696.9	716.4	725.5	738.2
643254	482.3	494.6	512.6	522.5	536.8

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: III-0

DOSE: 25 MG/KG/DAY

TEST DAYS:	78	85	92	99	106
ANIMAL NUMBER					
643287	469.8	473.5	480.6	490.8	495.4
643188	626.4	641.6	660.3	679.0	695.9
643230	495.5	513.5	530.1	538.7	541.3
643170	570.3	568.3	583.2	597.3	610.4
643144	477.4	485.6	496.3	504.1	513.9
643277	606.8	619.3	642.7	662.5	676.7
643214	566.9	567.9	583.2	595.4	612.9
643261	589.6	607.3	624.1	646.7	657.4
643166	549.5	568.7	580.6	597.8	613.5
643153	529.1	542.3	558.4	577.8	588.6
643177	558.2	578.2	585.8	583.8	592.1
643198	623.5	637.1	643.9	653.0	660.5
643291	574.0	581.1	596.7	614.6	623.5
643184	464.8	460.9	472.6	495.0	476.9
643167	554.3	579.6	583.1	597.7	605.2
643223	517.3	525.8	530.9	533.7	544.7
643233	465.1	480.6	493.3	511.3	518.4
643183	584.7	582.7	594.2	605.3	614.2
643219	569.3	590.0	615.9	629.5	636.2
643263	484.8	502.0	520.0	529.5	532.8

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: V-0

DOSE: 100 MG/KG/DAY

TEST DAYS:	78	85	92	99	106
ANIMAL NUMBER					
643313	511.6	515.1	527.8	538.8	536.6
643182	566.3	590.0	604.1	630.8	636.4
643146	558.8	576.7	597.7	611.8	610.9
643312	512.4	523.6	533.3	541.9	550.9
643199	543.0	556.5	551.1	552.8	554.2
643267	547.4	568.7	572.7	584.7	561.4
643216	592.5	614.7	622.7	629.1	581.4
643244	507.2	516.6	529.3	551.4	542.0
643245	466.6	474.0	489.0	496.6	493.4
643301	545.1	561.9	581.2	586.5	600.9
643200	560.7	576.0	592.4	605.6	610.9
643255	601.1	600.0	619.0	637.4	640.7
643157	552.8	571.6	585.7	599.9	605.3
643238	538.6	546.3	538.2	538.8	537.4
643227	568.5	582.1	591.1	601.2	616.0
643164	592.7	604.7	616.0	626.2	640.0
643154	499.6	505.8	520.2	495.1	497.4
643156	606.0	618.5	633.6	645.2	637.4
643208	526.7	530.6	531.9	540.9	465.9
643190	553.2	551.9	552.4	567.7	563.9

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: VII-0

DOSE: 250 MG/KG/DAY

TEST DAYS:	78	85	92	99	106
ANIMAL NUMBER					
643289	403.6	431.4	440.0	449.3	454.2
643171	536.3	572.0	592.9	611.8	627.6
643158	577.3	596.1	615.9	624.7	632.1
643249	499.4	528.9	554.9	565.8	576.7
643161	505.7	542.4	567.1	576.1	587.0
643248	429.6	457.8	464.5	419.4	397.7
643285	443.7	457.6	473.0	480.5	495.4
643278	490.4	501.4	507.7	523.8	534.0
643299	477.9	506.7	516.6	524.6	538.4
643274	491.0	508.7	511.0	515.1	518.9
643192	542.1	563.5	579.1	597.4	604.5
643222	513.5	512.7	529.7	536.6	538.3
643160	481.5	485.4	489.5	498.4	505.3
643191	509.4	519.2	538.3	528.8	529.7
643203	513.3	539.0	559.3	574.6	584.5
643282	578.4	599.4	626.8	654.0	674.5
643302	433.6	473.5	500.5	524.6	540.6
643317	447.6	472.1	478.8	486.1	496.8
643281	530.5	538.9	544.8	548.6	560.8

APPENDIX P

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ MALE RATS

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ MALE RATS

EXPLANATORY NOTES

Notes:

Test Days 75 – 89 = Cohabitation period

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: I-0

DOSE: 0 MG/KG/DAY

TEST DAYS:	78-85	85-92	92-99	99-106	78-106
ANIMAL NUMBER					
643239	11.4	13.5	-2.3	23.4	46.0
643270	25.5	12.9	10.0	6.8	55.2
643148	4.5	18.8	17.1	13.2	53.6
643284	19.6	3.4	17.4	16.2	56.6
643229	15.2	3.9	21.7	7.0	47.8
643196	13.9	10.8	16.9	10.4	52.0
643176	10.7	23.2	12.5	6.5	52.9
643218	11.0	20.1	12.5	18.0	61.6
643207	15.4	5.7	10.3	3.2	34.6
643280	18.7	8.1	11.3	16.8	54.9
643271	1.4	12.8	20.2	6.9	41.3
643211	15.0	10.6	19.0	11.5	56.1
643163	23.4	17.8	11.7	11.4	64.3
643197	14.9	16.4	8.0	13.0	52.3
643242	3.7	26.2	9.9	10.7	50.5
643251	14.3	18.7	5.2	14.0	52.2
643155	15.9	3.2	12.7	17.4	49.2
643147	11.4	13.7	12.2	5.7	43.0
643276	19.7	19.5	9.1	12.7	61.0
643254	12.3	18.0	9.9	14.3	54.5

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: III-0

DOSE: 25 MG/KG/DAY

TEST DAYS:	78-85	85-92	92-99	99-106	78-106
ANIMAL NUMBER					
643287	3.7	7.1	10.2	4.6	25.6
643188	15.2	18.7	18.7	16.9	69.5
643230	18.0	16.6	8.6	2.6	45.8
643170	-2.0	14.9	14.1	13.1	40.1
643144	8.2	10.7	7.8	9.8	36.5
643277	12.5	23.4	19.8	14.2	69.9
643214	1.0	15.3	12.2	17.5	46.0
643261	17.7	16.8	22.6	10.7	67.8
643166	19.2	11.9	17.2	15.7	64.0
643153	13.2	16.1	19.4	10.8	59.5
643177	20.0	7.6	-2.0	8.3	33.9
643198	13.6	6.8	9.1	7.5	37.0
643291	7.1	15.6	17.9	8.9	49.5
643184	-3.9	11.7	22.4	-18.1	12.1
643167	25.3	3.5	14.6	7.5	50.9
643223	8.5	5.1	2.8	11.0	27.4
643233	15.5	12.7	18.0	7.1	53.3
643183	-2.0	11.5	11.1	8.9	29.5
643219	20.7	25.9	13.6	6.7	66.9
643263	17.2	18.0	9.5	3.3	48.0

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: V-0

DOSE: 100 MG/KG/DAY

TEST DAYS:	78-85	85-92	92-99	99-106	78-106
ANIMAL NUMBER					
643313	3.5	12.7	11.0	-2.2	25.0
643182	23.7	14.1	26.7	5.6	70.1
643146	17.9	21.0	14.1	-0.9	52.1
643312	11.2	9.7	8.6	9.0	38.5
643199	13.5	-5.4	1.7	1.4	11.2
643267	21.3	4.0	12.0	-23.3	14.0
643216	22.2	8.0	6.4	-47.7	-11.1
643244	9.4	12.7	22.1	-9.4	34.8
643245	7.4	15.0	7.6	-3.2	26.8
643301	16.8	19.3	5.3	14.4	55.8
643200	15.3	16.4	13.2	5.3	50.2
643255	-1.1	19.0	18.4	3.3	39.6
643157	18.8	14.1	14.2	5.4	52.5
643238	7.7	-8.1	0.6	-1.4	-1.2
643227	13.6	9.0	10.1	14.8	47.5
643164	12.0	11.3	10.2	13.8	47.3
643154	6.2	14.4	-25.1	2.3	-2.2
643156	12.5	15.1	11.6	-7.8	31.4
643208	3.9	1.3	9.0	-75.0	-60.8
643190	-1.3	0.5	15.3	-3.8	10.7

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: VII-0

DOSE: 250 MG/KG/DAY

TEST DAYS:	78-85	85-92	92-99	99-106	78-106
ANIMAL NUMBER					
643289	27.8	8.6	9.3	4.9	50.6
643171	35.7	20.9	18.9	15.8	91.3
643158	18.8	19.8	8.8	7.4	54.8
643249	29.5	26.0	10.9	10.9	77.3
643161	36.7	24.7	9.0	10.9	81.3
643248	28.2	6.7	-45.1	-21.7	-31.9
643285	13.9	15.4	7.5	14.9	51.7
643278	11.0	6.3	16.1	10.2	43.6
643299	28.8	9.9	8.0	13.8	60.5
643274	17.7	2.3	4.1	3.8	27.9
643192	21.4	15.6	18.3	7.1	62.4
643222	-0.8	17.0	6.9	1.7	24.8
643160	3.9	4.1	8.9	6.9	23.8
643191	9.8	19.1	-9.5	0.9	20.3
643203	25.7	20.3	15.3	9.9	71.2
643282	21.0	27.4	27.2	20.5	96.1
643302	39.9	27.0	24.1	16.0	107.0
643317	24.5	6.7	7.3	10.7	49.2
643281	8.4	5.9	3.8	12.2	30.3

APPENDIX Q

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS OF P₁ FEMALE RATS DURING GESTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS OF P₁ FEMALE RATS DURING GESTATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered; data excluded from statistical analysis.
- b* No gestation data since no copulation plug was observed; no litter was delivered.
- c* Data not collected due to error.
- d* No litter delivered, however, implants were observed at necropsy. Data was excluded from statistical analysis.
- e* No gestation data since no plug was observed, however a litter was delivered.
- f* Dam delivered prior to collection of Day 21G body weight.
- g* Accidentally killed Test Day 91 (Day 14G).

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

GESTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643352 ^a	306.1	328.9	339.3	322.7
643343	274.2	294.4	322.4	394.4
643459	318.3	355.7	382.0	478.0
643394 ^a	302.2	333.8	344.3	349.9
643480	304.6	334.7	363.5	451.6
643319 ^b	-	-	-	-
643350 ^a	306.1	311.0	327.3	318.2
643363	336.7	361.8	400.1	476.5
643397	311.1	332.2	369.3	- ^c
643421	269.9	301.7	339.6	- ^c
643420 ^a	365.6	403.0	426.8	397.9
643419	357.8	396.0	428.2	533.9
643414 ^d	343.8	381.6	416.5	370.9
643401	269.6	299.9	332.9	421.3
643455	281.1	313.9	340.2	444.7
643378	359.5	383.3	419.9	471.9
643393 ^b	-	-	-	-
643447	322.0	350.3	394.3	- ^c
643478	281.7	308.9	340.8	433.1
643386	287.7	308.0	337.5	426.7

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: IV-0

DOSE: 25 MG/KG/DAY

GESTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643399	307.2	341.6	366.8	447.7
643334	292.4	317.4	358.6	- ^c
643464	327.7	348.1	386.5	- ^c
643369	309.8	352.4	386.7	499.2
643490	301.0	340.4	375.9	437.9
643342	345.8	375.2	412.3	511.0
643438	306.5	325.8	345.9	408.7
643445 ^a	391.8	415.8	434.8	422.7
643418	303.8	335.6	364.5	451.1
643325	363.9	404.7	388.7	555.5
643479 ^e	-	-	-	-
643403 ^a	297.8	323.0	333.3	313.9
643376	315.9	336.2	368.6	- ^f
643422 ^d	349.0	374.6	401.0	400.1
643452	336.1	375.7	392.3	445.3
643475	345.7	374.3	383.9	386.7
643372	315.4	339.9	358.4	489.6
643400	275.4	287.3	322.4	371.4
643395	289.7	316.7	339.3	- ^c
643457	307.2	339.9	368.8	- ^c

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: VI-0

DOSE: 100 MG/KG/DAY

GESTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643320	312.5	338.6	371.2	433.2
643488 ^a	288.9	311.2	326.3	308.7
643428	321.4	348.9	379.2	455.2
643439	294.8	327.5	360.1	463.4
643353	310.0	346.8	381.7	452.3
643385 ^a	310.4	312.8	331.6	301.9
643339	304.7	333.5	363.9	- ^c
643473 ^a	274.2	288.1	301.6	296.6
643337	315.0	341.1	377.7	- ^c
643416	271.5	301.1	329.5	385.2
643407	326.2	358.4	405.3	- ^c
643357 ^a	278.6	283.3	287.5	282.7
643331	313.6	336.7	366.4	410.5
643427	271.9	299.6	333.8	381.4
643470 ^b	-	-	-	-
643434	297.8	338.9	362.3	454.8
643349	304.1	345.1	376.0	498.7
643454	312.3	342.2	373.7	- ^c
643333	266.4	311.5	345.5	373.0
643460	309.6	331.7	363.1	451.8

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: VIII-0

DOSE: 250 MG/KG/DAY

GESTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643467	276.6	319.8	345.2	436.3
643443	255.0	300.5	336.0	415.1
643417	331.7	364.9	399.2	495.7
643413	284.5	307.1	341.1	433.6
643338	295.4	322.1	354.6	447.5
643335 ^e	-	-	-	-
643468	273.8	310.0	347.3	440.3
643440	292.0	327.6	363.4	476.6
643430 ^a	272.4	280.6	282.2	267.0
643431 ^b	-	-	-	-
643326	312.0	325.1	362.0	443.6
643365	318.5	350.8	369.8	435.4
643375	312.8	361.7	401.2	- ^c
643328	302.1	346.1	384.5	- ^c
643348 ^a	265.7	276.0	283.4	283.7
643346	307.5	263.6	- ^g	- ^g
643449	328.1	361.6	386.4	493.9
643429	314.1	348.0	382.6	371.4
643424 ^a	240.8	267.8	281.8	283.8

APPENDIX R

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ FEMALE RATS DURING GESTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ FEMALE RATS DURING GESTATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered; data excluded from statistical analysis.
- b* No gestation data since no copulation plug was observed; no litter was delivered.
- c* Data not collected due to error.
- d* No litter delivered, however, implants were observed at necropsy. Data was excluded from statistical analysis.
- e* No gestation data since no plug was observed, however a litter was delivered.
- f* Dam delivered prior to collection of day 21G body weight.
- g* Accidentally killed Test Day 91 (Day 14G).

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643352 ^a	22.8	10.4	-16.6	16.6
643343	20.2	28.0	72.0	120.2
643459	37.4	26.3	96.0	159.7
643394 ^a	31.6	10.5	5.6	47.7
643480	30.1	28.8	88.1	147.0
643319 ^b	-	-	-	-
643350 ^a	4.9	16.3	-9.1	12.1
643363	25.1	38.3	76.4	139.8
643397	21.1	37.1	-C	-C
643421	31.8	37.9	-C	-C
643420 ^a	37.4	23.8	-28.9	32.3
643419	38.2	32.2	105.7	176.1
643414 ^d	37.8	34.9	-45.6	27.1
643401	30.3	33.0	88.4	151.7
643455	32.8	26.3	104.5	163.6
643378	23.8	36.6	52.0	112.4
643393 ^b	-	-	-	-
643447	28.3	44.0	-C	-C
643478	27.2	31.9	92.3	151.4
643386	20.3	29.5	89.2	139.0

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: IV-0 .

DOSE: 25 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643399	34.4	25.2	80.9	140.5
643334	25.0	41.2	-C	-C
643464	20.4	38.4	-C	-C
643369	42.6	34.3	112.5	189.4
643490	39.4	35.5	62.0	136.9
643342	29.4	37.1	98.7	165.2
643438	19.3	20.1	62.8	102.2
643445 ^a	24.0	19.0	-12.1	30.9
643418	31.8	28.9	86.6	147.3
643325	40.8	-16.0	166.8	191.6
643479 ^e	-	-	-	-
643403 ^a	25.2	10.3	-19.4	16.1
643376	20.3	32.4	-f	-f
643422 ^d	25.6	26.4	-0.9	51.1
643452	39.6	16.6	53.0	109.2
643475	28.6	9.6	2.8	41.0
643372	24.5	18.5	131.2	174.2
643400	11.9	35.1	49.0	96.0
643395	27.0	22.6	-C	-C
643457	32.7	28.9	-C	-C

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: VI-0

DOSE: 100 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643320	26.1	32.6	62.0	120.7
643488 ^a	22.3	15.1	-17.6	19.8
643428	27.5	30.3	76.0	133.8
643439	32.7	32.6	103.3	168.6
643353	36.8	34.9	70.6	142.3
643385 ^a	2.4	18.8	-29.7	-8.5
643339	28.8	30.4	-C	-C
643473 ^a	13.9	13.5	-5.0	22.4
643337	26.1	36.6	-C	-C
643416	29.6	28.4	55.7	113.7
643407	32.2	46.9	-C	-C
643357 ^a	4.7	4.2	-4.8	4.1
643331	23.1	29.7	44.1	96.9
643427	27.7	34.2	47.6	109.5
643470 ^b	-	-	-	-
643434	41.1	23.4	92.5	157.0
643349	41.0	30.9	122.7	194.6
643454	29.9	31.5	-C	-C
643333	45.1	34.0	27.5	106.6
643460	22.1	31.4	88.7	142.2

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING GESTATION

GROUP: VIII-0

DOSE: 250 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643467	43.2	25.4	91.1	159.7
643443	45.5	35.5	79.1	160.1
643417	33.2	34.3	96.5	164.0
643413	22.6	34.0	92.5	149.1
643338	26.7	32.5	92.9	152.1
643335 ^e	-	-	-	-
643468	36.2	37.3	93.0	166.5
643440	35.6	35.8	113.2	184.6
643430 ^a	8.2	1.6	-15.2	-5.4
643431 ^b	-	-	-	-
643326	13.1	36.9	81.6	131.6
643365	32.3	19.0	65.6	116.9
643375	48.9	39.5	- ^c	- ^c
643328	44.0	38.4	- ^c	- ^c
643348 ^a	10.3	7.4	0.3	18.0
643346	-43.9	- ^g	- ^g	- ^g
643449	33.5	24.8	107.5	165.8
643429	33.9	34.6	-11.2	57.3
643424 ^a	27.0	14.0	2.0	43.0

APPENDIX S

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS OF P₁ FEMALE RATS DURING LACTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS OF P₁ FEMALE RATS DURING LACTATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered.
- b* No litter delivered, however, implants were observed at necropsy. Data was excluded from statistical analysis.
- c* Found Dead Test Day 99 (Day 22G).
- d* Accidentally killed Test Day 91 (Day 14G).
- e* Found dead Test Day 106 (Lactation Day 0).

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

LACTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643352 ^a	-	-	-	-
643343	297.4	319.1	335.8	336.3
643459	360.5	378.4	392.7	377.8
643394 ^a	-	-	-	-
643480	331.7	353.2	361.0	330.8
643319 ^a	-	-	-	-
643350 ^a	-	-	-	-
643363	367.4	380.0	392.4	379.1
643397	356.1	300.2	358.8	361.1
643421	320.1	320.1	283.8	286.3
643420 ^a	-	-	-	-
643419	412.6	398.0	414.8	402.9
643414 ^b	-	-	-	-
643401	312.9	324.1	338.7	324.0
643455	305.9	327.2	343.3	331.8
643378	389.9	372.2	375.9	376.7
643393 ^a	-	-	-	-
643447	387.7	376.9	387.2	365.9
643478	320.5	321.5	355.5	339.1
643386	329.0	339.2	347.9	354.3

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: IV-0

DOSE: 25 MG/KG/DAY

LACTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643399	340.9	352.7	387.6	342.4
643334	328.5	346.8	370.7	355.0
643464	369.8	306.1	385.7	391.5
643369	360.2	375.6	398.1	377.9
643490	325.7	354.9	388.4	353.7
643342	381.6	377.3	397.8	381.8
643438	336.3	339.9	368.7	352.0
643445 ^a	-	-	-	-
643418	352.7	353.4	368.1	346.4
643325	435.4	434.8	431.8	405.7
643479	341.2	301.7	370.2	358.6
643403 ^a	-	-	-	-
643376	343.9	337.0	371.9	366.9
643422 ^b	-	-	-	-
643452	324.7	334.1	375.4	375.0
643475	367.9	372.6	394.0	388.9
643372	363.1	347.0	374.3	346.7
643400	301.4	322.5	344.7	356.0
643395	336.2	345.5	364.6	350.5
643457	368.5	370.5	383.5	371.1

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: VI-0

DOSE: 100 MG/KG/DAY

LACTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643320	376.8	371.7	370.7	367.8
643488 ^a	-	-	-	-
643428	354.8	374.9	390.6	380.6
643439	353.1	353.0	374.6	363.0
643353	379.7	374.0	393.0	360.9
643385 ^a	-	-	-	-
643339	338.5	346.9	378.5	353.0
643473 ^a	-	-	-	-
643337	367.8	373.5	389.2	381.7
643416	330.7	319.5	350.1	341.5
643407	318.1	328.4	341.4	356.3
643357 ^a	-	-	-	-
643331	294.7	345.0	379.3	378.3
643427	292.9	334.4	341.2	329.2
643470 ^a	-	-	-	-
643434	335.9	355.2	376.9	360.8
643349	354.1	369.3	390.1	365.2
643454 ^c	-	-	-	-
643333	270.6	341.2	371.2	346.8
643460	353.6	313.3	353.0	360.0

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: VIII-0

DOSE: 250 MG/KG/DAY

LACTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
643467	345.3	350.1	362.8	345.4
643443	316.1	331.3	352.8	259.3
643417	388.9	408.9	415.0	306.4
643413	324.2	343.5	348.9	283.6
643338	328.8	341.2	371.8	357.6
643335	328.7	359.9	319.0	362.4
643468	319.8	322.9	348.4	319.3
643440	345.3	304.2	384.3	390.6
643430 ^a	-	-	-	-
643431 ^a	-	-	-	-
643326	336.2	348.6	375.2	361.5
643365	353.2	353.4	371.2	380.5
643375	365.3	366.3	368.3	378.7
643328	327.5	340.3	305.6	312.4
643348 ^a	-	-	-	-
643346 ^d	-	-	-	-
643449	363.0	370.6	391.2	377.1
643429 ^e	-	-	-	-
643424 ^a	-	-	-	-

APPENDIX T

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ FEMALE RATS DURING LACTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS OF P₁ FEMALE RATS DURING LACTATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered.
- b* No litter delivered, however, implants were observed at necropsy. Data were excluded from statistical analysis.
- c* Found Dead Test Day 99 (Day 22G).
- d* Accidentally killed Test Day 91 (Day 14G).
- e* Found Dead Test Day 106 (Lactation Day 0).

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

LACTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643352 ^a	-	-	-	-
643343	21.7	16.7	0.5	38.9
643459	17.9	14.3	-14.9	17.3
643394 ^a	-	-	-	-
643480	21.5	7.8	-30.2	-0.9
643319 ^a	-	-	-	-
643350 ^a	-	-	-	-
643363	12.6	12.4	-13.3	11.7
643397	-55.9	58.6	2.3	5.0
643421	0.0	-36.3	2.5	-33.8
643420 ^a	-	-	-	-
643419	-14.6	16.8	-11.9	-9.7
643414 ^b	-	-	-	-
643401	11.2	14.6	-14.7	11.1
643455	21.3	16.1	-11.5	25.9
643378	-17.7	3.7	0.8	-13.2
643393 ^a	-	-	-	-
643447	-10.8	10.3	-21.3	-21.8
643478	1.0	34.0	-16.4	18.6
643386	10.2	8.7	6.4	25.3

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: IV-0

DOSE: 25 MG/KG/DAY

LACTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643399	11.8	34.9	-45.2	1.5
643334	18.3	23.9	-15.7	26.5
643464	-63.7	79.6	5.8	21.7
643369	15.4	22.5	-20.2	17.7
643490	29.2	33.5	-34.7	28.0
643342	-4.3	20.5	-16.0	0.2
643438	3.6	28.8	-16.7	15.7
643445 ^a	-	-	-	-
643418	0.7	14.7	-21.7	-6.3
643325	-0.6	-3.0	-26.1	-29.7
643479	-39.5	68.5	-11.6	17.4
643403 ^a	-	-	-	-
643376	-6.9	34.9	-5.0	23.0
643422 ^b	-	-	-	-
643452	9.4	41.3	-0.4	50.3
643475	4.7	21.4	-5.1	21.0
643372	-16.1	27.3	-27.6	-16.4
643400	21.1	22.2	11.3	54.6
643395	9.3	19.1	-14.1	14.3
643457	2.0	13.0	-12.4	2.6

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: VI-0

DOSE: 100 MG/KG/DAY

LACTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643320	-5.1	-1.0	-2.9	-9.0
643488 ^a	-	-	-	-
643428	20.1	15.7	-10.0	25.8
643439	-0.1	21.6	-11.6	9.9
643353	-5.7	19.0	-32.1	-18.8
643385 ^a	-	-	-	-
643339	8.4	31.6	-25.5	14.5
643473 ^a	-	-	-	-
643337	5.7	15.7	-7.5	13.9
643416	-11.2	30.6	-8.6	10.8
643407	10.3	13.0	14.9	38.2
643357 ^a	-	-	-	-
643331	50.3	34.3	-1.0	83.6
643427	41.5	6.8	-12.0	36.3
643470 ^a	-	-	-	-
643434	19.3	21.7	-16.1	24.9
643349	15.2	20.8	-24.9	11.1
643454 ^c	-	-	-	-
643333	70.6	30.0	-24.4	76.2
643460	-40.3	39.7	7.0	6.4

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ FEMALE RATS DURING LACTATION

GROUP: VIII-0

DOSE: 250 MG/KG/DAY

LACTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643467	4.8	12.7	-17.4	0.1
643443	15.2	21.5	-93.5	-56.8
643417	20.0	6.1	-108.6	-82.5
643413	19.3	5.4	-65.3	-40.6
643338	12.4	30.6	-14.2	28.8
643335	31.2	-40.9	43.4	33.7
643468	3.1	25.5	-29.1	-0.5
643440	-41.1	80.1	6.3	45.3
643430 ^a	-	-	-	-
643431 ^a	-	-	-	-
643326	12.4	26.6	-13.7	25.3
643365	0.2	17.8	9.3	27.3
643375	1.0	2.0	10.4	13.4
643328	12.8	-34.7	6.8	-15.1
643348 ^a	-	-	-	-
643346 ^d	-	-	-	-
643449	7.6	20.6	-14.1	14.1
643429 ^e	-	-	-	-
643424 ^a	-	-	-	-

APPENDIX U

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL DAILY FOOD CONSUMPTION BY P₁ FEMALE RATS
DURING GESTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL DAILY FOOD CONSUMPTION BY P₁ FEMALE RATS
DURING GESTATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered; data excluded from statistical analysis.
- b* No gestation data since no plug was observed; no litter was delivered.
- c* No litter delivered, however, implants were observed at necropsy. Data were excluded from statistical analysis.
- d* No gestation data since no plug was observed, however a litter was delivered.
- e* Accidentally killed Test Day 91 (Day 14G).

INDIVIDUAL DAILY FOOD CONSUMPTION (grams) BY P₁ FEMALE RATS
DURING GESTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643352 ^a	24.5	25.8	19.8	23.4
643343	20.9	25.1	25.0	23.7
643459	26.3	27.7	25.2	26.4
643394 ^a	27.7	25.9	25.4	26.4
643480	15.4	30.3	9.0	18.2
643319 ^b	-	-	-	-
643350 ^a	21.6	26.3	21.8	23.2
643363	29.6	32.5	30.1	30.7
643397	25.9	28.1	28.4	27.5
643421	23.3	27.9	26.2	25.8
643420 ^a	34.6	35.1	22.1	30.6
643419	30.0	32.3	31.2	31.2
643414 ^c	30.8	29.4	23.6	27.9
643401	25.5	29.0	29.4	28.0
643455	23.2	37.1	24.6	28.3
643378	27.5	32.6	28.8	29.6
643393 ^b	-	-	-	-
643447	27.2	31.4	30.9	29.8
643478	25.3	27.2	26.3	26.3
643386	21.8	22.7	23.8	22.8

INDIVIDUAL DAILY FOOD CONSUMPTION (grams) BY P₁ FEMALE RATS
DURING GESTATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643399	23.8	28.3	27.8	26.6
643334	24.1	26.0	27.3	25.8
643464	23.4	26.1	27.1	25.5
643369	27.6	27.4	24.6	26.5
643490	27.8	28.8	27.0	27.9
643342	28.5	28.9	29.1	28.8
643438	20.4	22.4	26.4	23.1
643445 ^a	26.1	28.4	6.5	20.3
643418	25.2	26.5	24.8	25.5
643325	32.1	35.4	37.1	34.9
643479 ^d	-	-	-	-
643403 ^a	22.9	22.9	19.5	21.7
643376	22.6	24.6	26.4	24.6
643422 ^c	24.1	31.2	29.3	28.2
643452	27.1	27.4	26.6	27.0
643475	26.7	26.2	24.4	25.8
643372	21.5	22.3	32.5	25.4
643400	23.7	24.1	25.0	24.3
643395	24.0	23.5	22.9	23.5
643457	25.5	28.5	26.4	26.8

INDIVIDUAL DAILY FOOD CONSUMPTION (grams) BY P₁ FEMALE RATS
DURING GESTATION

GROUP: VI-0

DOSE: 100 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643320	26.8	32.4	29.5	29.6
643488 ^a	22.5	24.2	16.8	21.2
643428	25.6	27.7	26.7	26.7
643439	25.2	28.8	28.1	27.4
643353	28.3	30.1	30.5	29.6
643385 ^a	21.0	22.4	18.3	20.6
643339	26.8	27.6	28.7	27.7
643473 ^a	22.3	22.8	19.0	21.3
643337	23.3	29.8	33.4	28.8
643416	24.9	27.5	27.0	26.4
643407	27.9	30.7	26.8	28.5
643357 ^a	17.7	21.2	18.2	19.1
643331	22.9	27.2	22.3	24.1
643427	22.8	25.0	23.4	23.7
643470 ^b	-	-	-	-
643434	30.0	28.0	26.3	28.1
643349	25.6	26.7	21.5	24.6
643454	26.7	28.1	26.6	27.1
643333	26.9	29.8	26.6	27.8
643460	23.8	26.9	28.1	26.3

INDIVIDUAL DAILY FOOD CONSUMPTION (grams) BY P₁ FEMALE RATS
DURING GESTATION

GROUP: VIII-0

DOSE: 250 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
643467	32.1	30.2	31.7	31.3
643443	25.5	26.3	23.8	25.2
643417	27.0	26.4	24.3	25.9
643413	29.1	28.6	18.7	25.5
643338	25.3	29.4	32.4	29.0
643335 ^d	-	-	-	-
643468	26.7	27.7	28.9	27.8
643440	28.9	29.5	26.3	28.2
643430 ^a	25.4	22.1	17.3	21.6
643431 ^b	-	-	-	-
643326	25.1	27.7	28.7	27.2
643365	29.6	30.5	27.0	29.0
643375	27.7	31.7	30.0	29.8
643328	30.5	32.2	27.0	29.9
643348 ^a	24.0	24.2	23.9	24.0
643346	14.3	36.8	- ^e	- ^e
643449	31.0	26.1	28.8	28.7
643429	22.5	25.3	17.3	21.7
643424 ^a	19.4	22.7	21.0	21.0

APPENDIX V
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: I-0 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643239	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643270	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643148	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643284	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643229	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643196	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643176	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643218	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643207	ALOPECIA RIGHT FRONT PAW(S) ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 108	85 92	85 108
643280	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643271	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643211	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643163	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643197	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: I-0 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643242	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643251	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643155	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643147	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643276	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643254	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: III-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643287	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643188	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643230	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643170	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643144	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643277	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643214	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643261	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643166	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643153	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643177	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643198	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643291	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643184	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: III-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643167	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643223	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643233	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643183	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643219	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643263	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: V-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643313	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643182	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643146	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 107	85	107
643312	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643199	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643267	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643216	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643244	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643245	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643301	ALOPECIA LEFT FRONT PAW(S) ALOPECIA LEFT FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 108	85 85	108 108
643200	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643255	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643157	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643238	NO ABNORMALITIES DETECTED. SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: V-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643227	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643164	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643154	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643156	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643208	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643190	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: VII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643289	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643171	COLORED DISCHARGE RIGHT EYE(S) RED	85	92
	TEETH CLIPPED	85	85
	ALOPECIA BOTH FRONT LEG(S)	99	107
	ALOPECIA BOTH FRONT PAW(S)	99	107
	SACRIFICED BY DESIGN TEST DAY 107		
643158	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643249	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 107		
643161	TEETH CLIPPED	85	85
	SACRIFICED BY DESIGN TEST DAY 107		
643248	TEETH CLIPPED	85	92
	COLORED DISCHARGE NOSE BLACK	99	106
	COLORED DISCHARGE BOTH EYE(S) RED	99	106
	TEETH CROOKED	99	108
	COLORED DISCHARGE RIGHT EYE(S) RED	108	108
	SACRIFICED BY DESIGN TEST DAY 108		
643285	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643278	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643299	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 108		
643274	TEETH CLIPPED	85	85
	SACRIFICED BY DESIGN TEST DAY 108		
643192	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643222	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: VII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643160	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643191	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643203	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643282	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643302	TEETH CLIPPED SACRIFICED BY DESIGN TEST DAY 109	85	92
643317	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		
643281	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 109		

APPENDIX W

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS
DURING GESTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

EXPLANATORY NOTES

Footnotes

- a* Copulation plug observed but no litter delivered.
- b* Data not collected on day 21 due to error.
- c* No litter delivered, however, implantation sites observed at necropsy.

Notes

This appendix includes only signs from rats with copulation plug observed.

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643352 ^a	NO ABNORMALITIES DETECTED		
643343	NO ABNORMALITIES DETECTED		
643459	NO ABNORMALITIES DETECTED		
643394 ^a	NO ABNORMALITIES DETECTED		
643480	NO ABNORMALITIES DETECTED		
643350 ^a	NO ABNORMALITIES DETECTED		
643363	NO ABNORMALITIES DETECTED		
643397 ^b	NO ABNORMALITIES DETECTED		
643421 ^b	NO ABNORMALITIES DETECTED		
643420 ^a	ALOPECIA RIGHT FRONT LEG	21	21
	ALOPECIA RIGHT FRONT PAW	21	21
	ALOPECIA RIGHT SHOULDER	21	21
	SORE RIGHT SHOULDER	21	21
643419	NO ABNORMALITIES DETECTED		
643414 ^c	NO ABNORMALITIES DETECTED		
643401	NO ABNORMALITIES DETECTED		
643455	NO ABNORMALITIES DETECTED		
643378	NO ABNORMALITIES DETECTED		
643447 ^b	NO ABNORMALITIES DETECTED		
643478	NO ABNORMALITIES DETECTED		
643386	NO ABNORMALITIES DETECTED		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643399	NO ABNORMALITIES DETECTED		
643334 ^b	NO ABNORMALITIES DETECTED		
643464 ^b	NO ABNORMALITIES DETECTED		
643369	NO ABNORMALITIES DETECTED		
643490	NO ABNORMALITIES DETECTED		
643342	ALOPECIA RIGHT FRONT LEG(S) ALOPECIA BOTH FRONT LEG(S)	0 14	7 21
643438	NO ABNORMALITIES DETECTED		
643445 ^a	NO ABNORMALITIES DETECTED		
643418	NO ABNORMALITIES DETECTED		
643325	NO ABNORMALITIES DETECTED		
643403 ^a	NO ABNORMALITIES DETECTED		
643376	NO ABNORMALITIES DETECTED		
643422 ^c	NO ABNORMALITIES DETECTED		
643452	NO ABNORMALITIES DETECTED		
643475	NO ABNORMALITIES DETECTED		
643372	NO ABNORMALITIES DETECTED		
643400	NO ABNORMALITIES DETECTED		
643395 ^b	NO ABNORMALITIES DETECTED		
643457 ^b	NO ABNORMALITIES DETECTED		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643320	NO ABNORMALITIES DETECTED		
643488 ^a	NO ABNORMALITIES DETECTED		
643428	NO ABNORMALITIES DETECTED		
643439	NO ABNORMALITIES DETECTED		
643353	NO ABNORMALITIES DETECTED		
643385 ^a	NO ABNORMALITIES DETECTED		
643339 ^b	NO ABNORMALITIES DETECTED		
643473 ^a	NO ABNORMALITIES DETECTED		
643337 ^b	STAINED ABDOMEN YELLOW	0	0
643416	NO ABNORMALITIES DETECTED		
643407 ^b	ALOPECIA LEFT FRONT LEG(S)	7	14
643357 ^a	STAINED PERINEUM YELLOW	0	0
643331	NO ABNORMALITIES DETECTED		
643427	NO ABNORMALITIES DETECTED		
643434	NO ABNORMALITIES DETECTED		
643349	NO ABNORMALITIES DETECTED		
643454 ^b	FOUND DEAD 03/20/01 (Test Day 99)	22	22
643333	NO ABNORMALITIES DETECTED		
643460	ALOPECIA LEFT FRONT LEG(S)	0	7
	ALOPECIA BOTH FRONT LEG(S)	14	21

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643467	ALOPECIA LEFT HIND QUARTERS	0	21
	ALOPECIA RIGHT SIDE(S)	0	21
643443	NO ABNORMALITIES DETECTED		
643417	NO ABNORMALITIES DETECTED		
643413	NO ABNORMALITIES DETECTED		
643338	NO ABNORMALITIES DETECTED		
643468	NO ABNORMALITIES DETECTED		
643440	NO ABNORMALITIES DETECTED		
643430 ^a	STAINED PERINEUM YELLOW	0	0
	WET PERINEUM	0	0
643326	NO ABNORMALITIES DETECTED		
643365	NO ABNORMALITIES DETECTED		
643375	NO ABNORMALITIES DETECTED		
643328	NO ABNORMALITIES DETECTED		
643348 ^a	NO ABNORMALITIES DETECTED		
643346	ACCIDENTALLY KILLED 03/12/01 (Test Day 91)	14	14
643449	NO ABNORMALITIES DETECTED		
643429	ALOPECIA BOTH REAR LEG(S)	0	21
	ALOPECIA RIGHT FRONT LEG(S)	0	14
	TEETH CLIPPED	0	0
	ALOPECIA RIGHT FRONT PAW(S)	21	21
	DIARRHEA	21	21
	WET UNDERBODY	21	21
	STAINED FACE BROWN	21	21
	WEAK	21	21
643424 ^a	NO ABNORMALITIES DETECTED		

APPENDIX X

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS
DURING LACTATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

EXPLANATORY NOTES

Footnotes

- a* No copulation plug was observed, however, a litter was delivered.
- b* Found dead prior to collection of Day 0 lactation clinical signs.

Note

This appendix includes clinical observations from lactating rats only.

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643343	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643459	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643480	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643363	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643397	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643421	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643419	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643401	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643455	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643378	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 125		
643447	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643478	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643386	ALOPECIA LEFT FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 126	21	21

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643399	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 132		
643334	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643464	DISCHARGE VAGINAL OPENING RED SACRIFICED BY DESIGN TEST DAY 121	0	0
643369	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 119	7	21
643490	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 119		
643342	ALOPECIA BOTH FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 123	0	21
643438	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643418	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 125		
643325	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 123		
643479 ^a	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643376	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643452	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643475	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643372	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 122	7	21

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643400	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643395	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643457	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643320	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643428	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643439	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643353	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643339	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643337	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
643416	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643407	ALOPECIA BOTH FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 120	0	21
643331	COLORED DISCHARGE NOSE BROWN ABNORMAL GAIT OR MOBILITY HUNCHED OVER DISCHARGE VAGINAL OPENING RED SACRIFICED BY DESIGN TEST DAY 120	0 0 0 0	0 7 0 0
643427	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643434	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643349	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 121	14	21
643333	ALOPECIA RIGHT FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 120	21	21
643460	ALOPECIA BOTH FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 120	0	21

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
643467	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 125		
643443	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 119		
643417	TEETH CLIPPED ALOPECIA RIGHT FRONT LEG(S) ALOPECIA LEFT FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 119	7 14 21	7 21 21
643413	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643338	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643335 ^a	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643468	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 125		
643440	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643326	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643365	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
643375	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643328	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
643449	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 125		
643429 ^b	FOUND DEAD TEST DAY 106	0	0

APPENDIX Y

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS DURING PREMATING AND COHABITATION IN P₁ FEMALE RATS

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION
IN P₁ FEMALE RATS

EXPLANATORY NOTES

Footnotes:

- a* Mean cycle length was not calculable due to insufficient data.
- b* No evidence of copulation was found; animal was not pregnant.
- c* No precoital interval could be calculated since no evidence of copulation was found.
- d* No evidence of copulation was found, but animal was pregnant. Data were excluded from statistical analysis since the animal was pregnant during part of the estrous cycle evaluation.

Abbreviations:

--- = No Data

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION

GROUP II-0: 0 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF DAYS OF DATA COLLECTION	PERCENT OF DAYS IN ESTRUS	PERCENT OF DAYS IN DIESTRUS	PERCENT OF DAYS IN PROESTRUS	MEAN CYCLE LENGTH (days)	PRECOITAL INTERVAL (days)
643421	23	22	65	13	3.80	2
643397	22	23	50	27	4.00	2
643363	25	24	64	12	4.00	4
643350	27	89	7	4	--- ^a	6
643319 ^b	35	71	23	6	10.50	--- ^c
643480	24	21	75	4	4.00	3
643394	25	20	68	12	4.50	5
643459	21	19	71	10	5.33	1
643343	24	21	75	4	4.50	3
643352	22	27	73	0	4.00	1
643386	29	24	59	17	4.60	8
643478	25	24	68	8	4.00	4
643477	23	17	78	4	4.00	2
643393 ^b	35	26	54	20	4.00	--- ^c
643378	27	22	67	11	4.25	6
643455	24	25	58	17	5.00	4
643401	23	26	65	9	5.00	3
643414	22	32	50	18	4.00	1
643419	25	24	56	20	4.00	4
643420	30	23	63	13	6.50	10

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION

GROUP IV-0: 25 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF DAYS OF DATA COLLECTION	PERCENT OF DAYS IN ESTRUS	PERCENT OF DAYS IN DIESTRUS	PERCENT OF DAYS IN PROESTRUS	MEAN CYCLE LENGTH (days)	PRECOITAL INTERVAL (days)
643325	26	31	58	12	5.00	5
643418	27	26	70	4	4.20	7
643445	24	17	71	13	4.00	3
643438	24	8	79	13	7.33	3
643342	26	31	54	15	4.00	5
643490	22	23	73	5	4.00	1
643369	22	36	59	5	5.00	1
643464	23	13	78	9	4.00	2
643334	23	22	70	9	4.00	2
643399	34	18	68	15	4.83	13
643457	23	22	74	4	4.00	2
643395	23	13	70	17	5.00	2
643400	24	25	67	8	4.00	3
643372	25	24	48	28	4.00	4
643475	21	19	67	14	4.67	1
643452	22	27	55	18	4.67	1
643422	24	29	54	17	3.80	3
643376	23	22	57	22	4.00	3
643403	22	5	73	23	4.50	1
643479 ^d	35	17	74	9	4.75	---C

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION

GROUP VI-0: 100 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF DAYS OF DATA COLLECTION	PERCENT OF DAYS IN ESTRUS	PERCENT OF DAYS IN DIESTRUS	PERCENT OF DAYS IN PROESTRUS	MEAN CYCLE LENGTH (days)	PRECOITAL INTERVAL (days)
643416	25	20	76	4	5.00	4
643337	23	22	65	13	5.00	2
643473	25	24	68	8	4.75	4
643339	23	22	70	9	4.25	2
643385	21	24	67	10	5.00	1
643353	22	27	55	18	4.67	1
643439	25	20	60	20	4.00	4
643428	25	8	80	12	6.67	4
643488	25	28	60	12	4.50	4
643320	25	24	64	12	4.75	4
643460	21	10	62	29	3.75	1
643333	22	27	55	18	4.33	1
643454	23	26	61	13	4.50	2
643349	24	25	63	13	4.00	3
643434	25	20	76	4	4.00	4
643470 ^c	35	91	9	0	---a	---c
643427	24	8	71	21	6.00	3
643331	22	9	77	14	4.00	1
643357	22	32	55	14	4.00	1
643407	23	30	65	4	5.00	2

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION

GROUP VIII-0: 250 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF DAYS OF DATA COLLECTION	PERCENT OF DAYS IN ESTRUS	PERCENT OF DAYS IN DIESTRUS	PERCENT OF DAYS IN PROESTRUS	MEAN CYCLE LENGTH (days)	PRECOITAL INTERVAL (days)
643431 ^b	35	23	69	9	5.33	--- ^c
643430	22	18	68	14	4.33	1
643440	24	13	79	8	9.50	4
643468	27	7	78	15	6.00	6
643335 ^d	33	12	88	0	6.00	--- ^c
643338	24	21	67	13	4.25	4
643413	25	24	72	4	4.00	4
643417	22	23	59	18	4.00	1
643443	22	32	55	14	3.75	1
643467	27	7	70	22	4.00	6
643424	22	32	68	0	4.33	1
643429	29	10	69	21	4.40	8
643449	27	26	67	7	3.67	7
643346	22	14	82	5	4.00	2
643348	24	25	71	4	4.00	4
643328	23	17	70	13	5.33	2
643375	23	13	74	13	5.00	2
643365	24	25	58	17	5.00	4
643326	25	24	64	12	4.00	4

APPENDIX Z

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND
COHABITATION IN P₁ FEMALE RATS

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND
COHABITATION IN P₁ FEMALE RATS

EXPLANATORY NOTES

Notes:

Test Days 54-75 = Premating
Test Days 75-88 = Cohabitation period

Abbreviations:

D = Diestrus
E = Estrus
P = Proestrus
X = No sample or stage could not be defined from sample.

Footnotes:

^a No evidence of copulation was found; animal was not pregnant.
^b No evidence of copulation was found; animal was pregnant.

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP II-0: 0 MG/KG/DAY

ANIMAL	TEST DAYS																																				
NUMBER	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88		
643421	P	D	D	E	D	D	D	E	D	D	D	E	D	D	P	E	D	D	D	E	D	D	P														
643397	D	D	P	E	D	D	P	E	X	D	D	D	D	D	P	E	D	D	P	E	D	D	P														
643363	D	E	D	D	P	E	D	D	P	E	D	D	D	D	E	D	D	E	D	D	P	E	D	D	D												
643350	E	E	E	D	E	E	E	D	P	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	
643319	E	D	D	P	E	E	D	D	D	D	D	P	E	E	E	E	E	E	E	E	E	E	D	D	E	E	E	E	E	E	E	E	E	E	E	E	
643480	E	D	D	D	E	D	D	D	P	D	D	D	D	D	E	D	D	E	D	D	D	E	D	D	D												
643394	D	D	E	D	D	D	P	E	E	D	D	D	D	D	P	D	D	P	E	D	D	D	D	D	D	X											
643459	D	D	E	D	D	D	E	D	D	D	P	E	D	D	D	X	D	D	D	E	D	D	P														
643343	D	E	D	D	D	E	D	D	D	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D												
643352	D	D	E	D	D	D	E	D	D	D	D	D	D	D	D	E	D	D	E	D	D	D	D														
643386	D	E	E	D	D	P	E	E	D	D	D	P	E	D	D	D	D	P	E	D	D	D	D	D	D	D	P	D	D	P							
643478	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	P	D	D	P												
643447	D	D	D	E	D	D	D	D	P	D	D	D	D	D	D	D	D	D	D	E	D	D	D														
643393	D	E	D	D	P	E	D	D	D	D	D	D	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	P	E	D	D	P	E	D	
643378	D	D	D	E	D	D	D	P	D	D	D	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	P	E									
643455	D	E	D	D	P	X	D	D	D	D	E	D	D	P	E	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D
643401	E	D	D	D	P	E	D	D	D	E	X	D	D	D	D	E	D	D	D	D	P	E	D	D	D	D											
643414	D	P	D	D	P	E	D	D	D	P	E	D	D	D	P	E	D	D	D	E	E	E															
643419	D	E	D	D	P	E	D	D	D	E	D	D	D	D	P	E	D	D	P	E	D	D	D	D	D	P											
643420	P	D	D	D	D	D	D	X	D	D	D	P	E	D	D	D	E	D	D	D	E	D	D	D	D	D	P	E	D	D	D	P	E				

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP IV-0: 25 MG/KG/DAY

ANIMAL		TEST DAYS																																		
NUMBER	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	
643325	E	E	D	D	D	P	E	D	D	D	P	E	D	D	D	E	E	D	D	D	P	E	D	D	D	E										
643418	D	D	E	D	D	D	E	D	D	D	E	D	D	D	E	X	D	D	D	D	D	P	E	D	D	D	D	D								
643445	D	P	E	D	D	D	P	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643438	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643342	D	D	E	D	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	E										
643490	D	D	E	D	D	D	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D													
643369	D	D	E	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643464	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643334	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643399	E	D	D	D	P	E	D	D	D	P	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	P	E	D	D	D	P	
643457	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D													
643395	D	D	D	D	P	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D												
643400	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
643372	P	E	D	D	P	E	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643475	D	D	X	E	D	D	D	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D													
643452	D	D	E	E	D	D	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D													
643422	P	E	D	D	P	E	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643376	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643403	D	P	D	D	D	P	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643479	D	P	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP VI-0: 100 MG/KG/DAY

ANIMAL	TEST DAYS																																			
NUMBER	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	
643416	D	E	D	D	D	D	D	D	D	D	D	D	P	E	D	D	D	D	D	D	D	E	D	D	D											
643337	D	D	D	P	E	D	D	D	D	E	D	D	D	P	E	D	D	D	D	P	E	D	D													
643473	D	E	D	D	D	D	E	D	D	D	P	E	D	D	D	P	E	D	D	D	D	D	D	D	D											
643339	D	D	E	D	D	D	E	D	D	D	P	E	D	D	D	E	D	D	D	E	D	D	P													
643385	D	D	D	P	E	D	D	D	X	E	D	D	D	D	P	E	D	D	D	E	D	D														
643353	D	E	E	D	D	D	P	E	D	D	D	D	P	D	D	P	E	E	D	D	P	E														
643439	D	P	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	P	E	D	D	P	D	D	P											
643428	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D											
643488	D	D	P	E	D	D	D	D	E	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D											
643320	P	D	D	P	E	D	D	D	D	E	D	D	D	X	E	D	D	P	P	D	D	P														
643460	D	D	P	E	D	D	D	D	P	D	D	P	D	D	D	D	D	D	D	D	D	P														
643333	D	D	E	D	D	D	P	E	D	D	D	P	E	D	D	P	E	D	D	D	P	E														
643454	D	E	D	D	P	E	D	D	D	E	D	D	D	D	P	E	D	D	P	E	D	D	D													
643349	E	D	D	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	P												
643434	D	E	D	D	D	D	P	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D											
643470	D	E	E	E	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	D	E	E	E	E	E	E	E	E	E	E	E	
643427	D	P	D	D	D	D	D	D	D	P	D	D	D	D	P	E	D	D	D	P	E	D	D	P												
643331	D	D	P	D	D	D	P	D	D	D	E	D	D	D	D	P	D	D	D	E	D	D														
643357	E	D	D	P	E	D	D	D	E	D	D	D	P	E	D	D	P	E	D	D	D	D														
643407	D	D	E	D	D	D	D	D	E	D	D	D	P	E	D	D	D	E	D	D	D	D	E													

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP VIII-0: 250 MG/KG/DAY

ANIMAL		TEST DAYS																																			
NUMBER		54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	
643431		P	E	D	D	D	D	E	D	D	D	E	D	D	D	E	D	D	D	P	E	D	D	D	D	E	D	D	D	D	D	D	D	D	P	E	D
643430		D	D	P	E	D	D	D	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D													
643440		D	D	E	D	D	D	D	D	X	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643468		D	P	E	D	D	D	D	D	P	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643335		D	D	E	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643338		E	D	D	D	P	E	D	D	D	E	D	D	P	E	D	D	D	P	E	D	D	D	D	D	D	X	D	D	D	D	D	D	D	D	D	
643413		D	E	D	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643417		P	E	D	D	D	D	D	D	D	P	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643443		E	E	E	D	D	P	D	D	D	P	E	D	D	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643467		P	E	D	D	D	P	D	D	D	P	D	D	D	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643424		D	D	D	E	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643429		D	D	E	D	D	D	D	P	D	D	P	D	D	D	D	D	D	D	D	P	E	D	D	D	P	E	D	D	D	D	D	D	D	D	D	
643449		E	E	D	D	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643346		D	D	D	P	D	D	D	D	D	D	D	E	D	D	D	E	D	D	D	D	D	D	X													
643348		D	E	D	D	D	D	E	D	X	D	D	D	D	D	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643328		D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643375		D	D	D	E	D	D	D	D	E	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643365		P	E	D	D	D	X	D	P	E	D	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	
643326		D	E	D	D	D	E	D	D	P	E	D	D	D	E	D	D	P	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	

APPENDIX AA

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL ANIMAL SPERM MOTILITY DATA IN P₁ MALE RATS

INDIVIDUAL ANIMAL SPERM MOTILITY DATA IN P₁ MALE RATS

GROUP I-0 0 MG/KG/DAY		GROUP III-0 25 MG/KG/DAY	
Animal Number	Percent Motile	Animal Number	Percent Motile
643239	93	643287	89
643270	90	643188	92
643148	95	643230	78
643284	99	643170	98
643229	96	643144	95
643196	91	643277	92
643176	86	643214	91
643218	94	643261	93
643207	95	643166	96
643280	94	643153	98

GROUP V-0 100 MG/KG/DAY		GROUP VII-0 250 MG/KG/DAY	
Animal Number	Percent Motile	Animal Number	Percent Motile
643313	96	643289	80
643182	91	643171	89
643146	96	643158	97
643312	84	643249	95
643199	93	643161	95
643267	95	643248	92
643216	96	643285	81
643244	92	643278	89
643245	98	643299	97
643301	92	643274	88

APPENDIX BB

INDIVIDUAL ANIMAL SPERM MORPHOLOGY DATA IN P₁ MALE RATS

INDIVIDUAL ANIMAL SPERM MORPHOLOGY DATA IN P₁ MALE RATS

GROUP I-0: 0 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
643239	199	1	0	0	99.5
643270	200	0	0	0	100.0
643148	195	0	5	0	97.5
643284	197	0	3	0	98.5
643229	199	1	0	0	99.5
643196	198	0	2	0	99.0
643176	197	1	2	0	98.5
643218	197	0	3	0	98.5
643207	196	2	2	0	98.0
643280	198	0	2	0	99.0

GROUP III-0: 25 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
643287	199	0	1	0	99.5
643188	199	0	1	0	99.5
643230	198	0	2	0	99.0
643170	198	0	2	0	99.0
643144	199	0	1	0	99.5
643277	199	1	0	0	99.5
643214	192	2	6	0	96.0
643261	200	0	0	0	100.0
643166	198	0	2	0	99.0
643153	197	1	2	0	98.5

INDIVIDUAL ANIMAL SPERM MORPHOLOGY DATA IN P₁ MALE RATS

GROUP V-0: 100 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
643313	195	0	5	0	97.5
643182	198	1	1	0	99.0
643146	198	1	1	0	99.0
643312	200	0	0	0	100.0
643199	199	0	1	0	99.5
643267	199	0	1	0	99.5
643216	199	0	1	0	99.5
643244	198	1	1	0	99.0
643245	198	1	1	0	99.0
643301	199	0	1	0	99.5

GROUP VII-0: 250 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
643289	196	2	2	0	98.0
643171	193	6	1	0	96.5
643158	199	1	0	0	99.5
643249	200	0	0	0	100.0
643161	197	0	3	0	98.5
643248	200	0	0	0	100.0
643285	197	0	3	0	98.5
643278	198	0	2	0	99.0
643299	200	0	0	0	100.0
643274	197	0	3	0	98.5

APPENDIX CC

INDIVIDUAL ANIMAL SPERM AND SPERMATID COUNTS IN P₁ MALE RATS

INDIVIDUAL ANIMAL SPERM AND SPERMATID COUNTS (Millions) IN P₁ MALE RATS

GROUP I-0: 0 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
643239	311.0	1067.8	109.9	69.0
643270	299.3	1249.0	128.0	81.3
643148	256.0	758.6	147.9	90.0
643284	254.9	858.1	131.0	84.2
643229	311.0	1002.4	144.4	86.4
643196	341.4	1154.4	151.4	103.0
643176	332.0	1195.5	146.7	100.5
643218	332.0	1216.1	103.5	65.4
643207	282.9	869.1	118.7	75.1
643280	266.6	938.2	119.3	89.8

GROUP III-0: 25 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
643287	274.2	1191.1	114.0	94.8
643188	229.1	850.8	112.2	66.5
643230	272.4	906.7	118.7	74.0
643170	346.0	1045.1	136.8	79.8
643144	280.6	1131.3	107.0	88.4
643277	225.6	836.3	152.6	110.5
643214	280.6	934.9	122.8	79.6
643261	254.9	899.9	124.5	86.2
643166	337.9	1238.4	114.6	81.4
643153	296.9	948.4	114.6	83.3

INDIVIDUAL ANIMAL SPERM AND SPERMATID COUNTS (Millions) IN P₁ MALE RATS

GROUP V-0: 100 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
643313	339.0	1239.5	154.3	106.3
643182	285.3	945.8	158.4	101.0
643146	301.6	970.4	166.0	103.1
643312	240.8	723.6	135.0	81.1
643199	261.9	879.6	168.4	98.0
643267	321.5	1054.7	154.9	91.4
643216	187.1	690.2	163.7	108.3
643244	249.0	884.2	162.5	102.6
643245	281.7	910.9	166.6	106.1
643301	312.1	1198.6	169.5	112.8

GROUP VII-0: 250 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
643289	368.3	1280.8	144.4	96.1
643171	282.9	894.7	119.8	94.0
643158	327.3	884.9	133.9	79.1
643249	328.5	977.7	122.2	81.5
643161	426.7	1116.7	161.3	101.8
643248	244.3	906.9	154.3	99.4
643285	231.5	742.6	166.0	110.8
643278	318.0	897.5	169.5	87.3
643299	245.5	859.3	151.4	91.3
643274	218.6	895.6	142.6	90.7

APPENDIX DD

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

EXPLANATORY NOTES

Notes:

Column labeled "Plug Observed"

- + indicates that a copulatory plug was observed
- **indicates that no copulatory plug was observed**

Column labeled "Litter Produced"

- + indicates that a litter was produced
- indicates that no litter was produced

Footnotes:

- a* No litter delivered, however, implantation sites were observed at necropsy.
- b* No copulation plug was observed, however, a litter was delivered. Gestation length unknown.
- c* Found dead on Day 22G (Test Day 99).
- d* Accidentally killed on Day 14G (Test Day 91).
- e* Found dead on Lactation Day 0 (Test Day 106).

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

GROUPS: II-0, I-0 DOSE: 0 MG/KG/DAY

FEMALE ANIMAL#	MALE #1 ANIMAL#	PLUG OBSERVED	MALE #2 ANIMAL#	PLUG OBSERVED	LITTER PRODUCED	GESTATION LENGTH (days)
643352	643239	+			-	--
643343	643270	+			+	23
643459	643148	+			+	23
643394	643284	+			-	--
643480	643229	+			+	23
643319	643196	-			-	--
643350	643176	+			-	--
643363	643218	+			+	22
643397	643207	+			+	22
643421	643280	+			+	22
643420	643271	+			-	--
643419	643211	+			+	22
643414 ^a	643163	+			-	--
643401	643197	+			+	22
643455	643242	+			+	22
643378	643251	+			+	23
643393	643155	-			-	--
643447	643147	+			+	22
643478	643276	+			+	22
643386	643254	+			+	22

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

GROUPS: IV-0, III-0 DOSE: 25 MG/KG/DAY

FEMALE ANIMAL#	MALE #1 ANIMAL#	PLUG OBSERVED	MALE #2 ANIMAL#	PLUG OBSERVED	LITTER PRODUCED	GESTATION LENGTH (days)
643399	643287	+			+	23
643334	643188	+			+	22
643464	643230	+			+	23
643369	643170	+			+	22
643490	643144	+			+	22
643342	643277	+			+	22
643438	643214	+			+	22
643445	643261	+			-	--
643418	643166	+			+	22
643325	643153	+			+	22
643479 ^b	643177	-			+	--
643403	643198	+			-	--
643376	643291	+			+	21
643422 ^a	643184	+			-	--
643452	643167	+			+	23
643475	643223	+			+	23
643372	643233	+			+	22
643400	643183	+			+	22
643395	643219	+			+	22
643457	643263	+			+	22

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

GROUPS: VI-0, V-0 DOSE: 100 MG/KG/DAY

FEMALE ANIMAL#	MALE #1 ANIMAL#	PLUG OBSERVED	MALE #2 ANIMAL#	PLUG OBSERVED	LITTER PRODUCED	GESTATION LENGTH (days)
643320	643313	+			+	22
643488	643182	+			-	--
643428	643146	+			+	22
643439	643312	+			+	22
643353	643199	+			+	23
643385	643267	+			-	--
643339	643216	+			+	22
643473	643244	+			-	--
643337	643245	+			+	22
643416	643301	+			+	22
643407	643200	+			+	22
643357	643255	+			-	--
643331	643157	+			+	23
643427	643238	+			+	23
643470	643227	-			-	--
643434	643164	+			+	22
643349	643154	+			+	22
643454 ^C	643156	+			-	--
643333	643208	+			+	23
643460	643190	+			+	23

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

GROUPS: VIII-0, VII-0 DOSE: 250 MG/KG/DAY

FEMALE ANIMAL#	MALE #1 ANIMAL#	PLUG OBSERVED	MALE #2 ANIMAL#	PLUG OBSERVED	LITTER PRODUCED	GESTATION LENGTH (days)
643467	643289	+			+	23
643443	643171	+			+	22
643417	643158	+			+	22
643413	643249	+			+	22
643338	643161	+			+	22
643335 ^b	643274	-			+	--
643468	643248	+			+	23
643440	643285	+			+	22
643430	643278	+			-	--
643431	643299	-			-	--
643326	643192	+			+	22
643365	643222	+			+	22
643375	643160	+			+	23
643328	643191	+			+	23
643348	643203	+			-	--
643346 ^d	643282	+			-	--
643449	643302	+			+	22
643429 ^e	643317	+			+	23
643424	643281	+			-	--

APPENDIX EE

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

EXPLANATORY NOTES

Footnotes:

- a* No implantation efficiency can be calculated.
- b* No litter produced; no implantation efficiency calculated.
- c* Found dead Day 22G (Test Day 99); the uterus contained 17 fetuses.
- d* Accidentally killed Day 14G (Test Day 91); the uterus contained 12 fetuses.
- e* Found dead Lactation Day 0 (Test Day 106).

Abbreviations:

--- = No data

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

GROUPS: II-0

DOSE: 0 MG/KG/DAY

Animal Number	Pups Born	Number of Implantation Sites	Implantation Efficiency
643343	12	10	---a
643459	15	16	93.8
643480	15	15	100.0
643363	17	18	94.4
643397	16	17	94.1
643421	12	13	92.3
643419	16	15	---a
643414 ^b	0	2	---
643401	15	16	93.8
643455	16	16	100.0
643378	8	8	100.0
643447	19	19	100.0
643478	15	15	100.0
643386	15	16	93.8

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

GROUPS: IV-0 DOSE: 25 MG/KG/DAY

Animal Number	Pups Born	Number of Implantation Sites	Implantation Efficiency
643399	14	17	82.4
643334	15	16	93.8
643464	14	14	100.0
643369	18	14	---a
643490	14	14	100.0
643342	16	16	100.0
643438	14	17	82.4
643418	15	15	100.0
643325	15	16	93.8
643479	7	9	77.8
643376	15	16	93.8
643422 ^b	0	2	---
643452	12	15	80.0
643475	2	4	50.0
643372	17	18	94.4
643400	15	15	100.0
643395	8	8	100.0
643457	16	16	100.0

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

GROUPS: VI-0

DOSE: 100 MG/KG/DAY

Animal Number	Pups Born	Number of Implantation Sites	Implantation Efficiency
643320	6	15	40.0
643428	14	16	87.5
643439	14	16	87.5
643353	9	11	81.8
643339	15	16	93.8
643337	15	17	88.2
643416	6	8	75.0
643407	16	14	--- ^a
643331	9	12	75.0
643427	14	15	93.3
643434	16	14	--- ^a
643349	18	18	100.0
643454 ^c	---	17	---
643333	7	9	77.8
643460	14	14	100.0

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

GROUPS: VIII-0

DOSE: 250 MG/KG/DAY

Animal Number	Pups Born	Number of Implantation Sites	Implantation Efficiency
643467	13	12	---a
643443	12	11	---a
643417	10	13	76.9
643413	12	12	100.0
643338	14	16	87.5
643335	14	16	87.5
643468	14	18	77.8
643440	18	18	100.0
643326	14	16	87.5
643365	9	8	---a
643375	5	14	35.7
643328	11	12	91.7
643346 ^d	---	12	---
643449	17	17	100.0
643429 ^e	16	15	---a

APPENDIX FF

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

EXPLANATORY NOTES

Footnotes:

- a* No litter delivered.
- b* Found dead test day 99 (Day 22G).
- c* Accidentally killed test day 91 (Day 14G); no litter was delivered.
- d* Found dead test day 106 (Lactation Day 0); data excluded from statistical analysis.
- e* Number born includes 13 unsexable fetuses.

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF PUPS						
	BORN	BORN ALIVE	PRECULLING		POSTCULLING		DAY 21
			DAY 4	DAY 4	DAY 7	DAY 14	
643352 ^a	-	-	-	-	-	-	-
643343	12	12	12	8	8	8	8
643459	15	15	15	8	8	8	8
643394 ^a	-	-	-	-	-	-	-
643480	15	15	15	8	8	8	8
643319 ^a	-	-	-	-	-	-	-
643350 ^a	-	-	-	-	-	-	-
643363	17	17	17	8	8	8	8
643397	16	16	16	8	8	8	8
643421	12	12	12	8	8	8	8
643420 ^a	-	-	-	-	-	-	-
643419	16	16	16	8	8	8	8
643414 ^a	-	-	-	-	-	-	-
643401	15	15	15	8	8	8	8
643455	16	15	15	8	8	8	8
643378	8	8	8	8	8	8	8
643393 ^a	-	-	-	-	-	-	-
643447	19	19	19	8	8	8	8
643478	15	15	15	8	8	8	8
643386	15	15	15	8	8	8	8

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF MALE PUPS						
	BORN	BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
643352 ^a	-	-	-	-	-	-	-
643343	6	6	6	4	4	4	4
643459	12	12	12	5	5	5	5
643394 ^a	-	-	-	-	-	-	-
643480	6	6	6	4	4	4	4
643319 ^a	-	-	-	-	-	-	-
643350 ^a	-	-	-	-	-	-	-
643363	7	7	7	4	4	4	4
643397	8	8	8	4	4	4	4
643421	6	6	6	4	4	4	4
643420 ^a	-	-	-	-	-	-	-
643419	11	11	11	4	4	4	4
643414 ^a	-	-	-	-	-	-	-
643401	12	12	12	5	5	5	5
643455	10	9	9	4	4	4	4
643378	5	5	5	5	5	5	5
643393 ^a	-	-	-	-	-	-	-
643447	12	12	12	4	4	4	4
643478	8	8	8	4	4	4	4
643386	10	10	10	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

NUMBER OF FEMALE PUPS							
ANIMAL NUMBER	BORN	BORN	PRECULLING	POSTCULLING		DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4	DAY 7		
643352 ^a	-	-	-	-	-	-	-
643343	6	6	6	4	4	4	4
643459	3	3	3	3	3	3	3
643394 ^a	-	-	-	-	-	-	-
643480	9	9	9	4	4	4	4
643319 ^a	-	-	-	-	-	-	-
643350 ^a	-	-	-	-	-	-	-
643363	10	10	10	4	4	4	4
643397	8	8	8	4	4	4	4
643421	6	6	6	4	4	4	4
643420 ^a	-	-	-	-	-	-	-
643419	5	5	5	4	4	4	4
643414 ^a	-	-	-	-	-	-	-
643401	3	3	3	3	3	3	3
643455	6	6	6	4	4	4	4
643378	3	3	3	3	3	3	3
643393 ^a	-	-	-	-	-	-	-
643447	7	7	7	4	4	4	4
643478	7	7	7	4	4	4	4
643386	5	5	5	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

NUMBER OF PUPS				LACTATION
ANIMAL NUMBER	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	INDEX
643352 ^a	-	-	-	-
643343	0.50	100.0	100.0	100.0
643459	0.80	100.0	100.0	100.0
643394 ^a	-	-	-	-
643480	0.40	100.0	100.0	100.0
643319 ^a	-	-	-	-
643350 ^a	-	-	-	-
643363	0.41	100.0	100.0	100.0
643397	0.50	100.0	100.0	100.0
643421	0.50	100.0	100.0	100.0
643420 ^a	-	-	-	-
643419	0.69	100.0	100.0	100.0
643414 ^a	-	-	-	-
643401	0.80	100.0	100.0	100.0
643455	0.63	93.8	100.0	100.0
643378	0.63	100.0	100.0	100.0
643393 ^a	-	-	-	-
643447	0.63	100.0	100.0	100.0
643478	0.53	100.0	100.0	100.0
643386	0.67	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

NUMBER OF MALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643352 ^a	-	-	-
643343	100.0	100.0	100.0
643459	100.0	100.0	100.0
643394 ^a	-	-	-
643480	100.0	100.0	100.0
643319 ^a	-	-	-
643350a	-	-	-
643363	100.0	100.0	100.0
643397	100.0	100.0	100.0
643421	100.0	100.0	100.0
643420 ^a	-	-	-
643419	100.0	100.0	100.0
643414 ^a	-	-	-
643401	100.0	100.0	100.0
643455	90.0	100.0	100.0
643378	100.0	100.0	100.0
643393 ^a	-	-	-
643447	100.0	100.0	100.0
643478	100.0	100.0	100.0
643386	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

NUMBER OF FEMALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643352 ^a	-	-	-
643343	100.0	100.0	100.0
643459	100.0	100.0	100.0
643394 ^a	-	-	-
643480	100.0	100.0	100.0
643319 ^a	-	-	-
643350 ^a	-	-	-
643363	100.0	100.0	100.0
643397	100.0	100.0	100.0
643421	100.0	100.0	100.0
643420 ^a	-	-	-
643419	100.0	100.0	100.0
643414 ^a	-	-	-
643401	100.0	100.0	100.0
643455	100.0	100.0	100.0
643378	100.0	100.0	100.0
643393 ^a	-	-	-
643447	100.0	100.0	100.0
643478	100.0	100.0	100.0
643386	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF PUPS					
		BORN	PRECULLING		POSTCULLING		DAY 21
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	
643399	14	14	14	8	8	8	8
643334	15	15	15	8	8	8	8
643464	14	14	14	8	8	8	8
643369	18	18	18	8	8	8	8
643490	14	14	14	8	8	8	8
643342	16	16	16	8	8	8	8
643438	14	14	13	8	8	8	8
643445 ^a	-	-	-	-	-	-	-
643418	15	15	13	8	8	8	8
643325	15	15	15	8	8	8	8
643479	7	7	7	7	7	7	7
643403 ^a	-	-	-	-	-	-	-
643376	15	14	14	8	8	8	8
643422 ^a	-	-	-	-	-	-	-
643452	12	12	12	8	8	8	8
643475	2	2	2	2	2	2	2
643372	17	17	17	8	8	8	8
643400	15	14	12	8	8	8	8
643395	8	8	8	8	8	8	8
643457	16	16	15	8	8	8	8

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF MALE PUPS					
		BORN	PRECULLING	POSTCULLING			
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
643399	6	6	6	4	4	4	4
643334	10	10	10	4	4	4	4
643464	5	5	5	4	4	4	4
643369	7	7	7	4	4	4	4
643490	10	10	10	4	4	4	4
643342	8	8	8	4	4	4	4
643438	6	6	6	4	4	4	4
643445 ^a	-	-	-	-	-	-	-
643418	8	8	7	4	4	4	4
643325	11	11	11	4	4	4	4
643479	1	1	1	1	1	1	1
643403 ^a	-	-	-	-	-	-	-
643376	11	10	10	4	4	4	4
643422 ^a	-	-	-	-	-	-	-
643452	7	7	7	4	4	4	4
643475	0	0	0	0	0	0	0
643372	10	10	10	4	4	4	4
643400	9	8	8	4	4	4	4
643395	4	4	4	4	4	4	4
643457	10	10	10	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF FEMALE PUPS					
		BORN	PRECULLING	POSTCULLING			
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
643399	8	8	8	4	4	4	4
643334	5	5	5	4	4	4	4
643464	9	9	9	4	4	4	4
643369	11	11	11	4	4	4	4
643490	4	4	4	4	4	4	4
643342	8	8	8	4	4	4	4
643438	8	8	7	4	4	4	4
643445 ^a	-	-	-	-	-	-	-
643418	7	7	6	4	4	4	4
643325	4	4	4	4	4	4	4
643479	6	6	6	6	6	6	6
643403 ^a	-	-	-	-	-	-	-
643376	4	4	4	4	4	4	4
643422 ^a	-	-	-	-	-	-	-
643452	5	5	5	4	4	4	4
643475	2	2	2	2	2	2	2
643372	7	7	7	4	4	4	4
643400	6	6	4	4	4	4	4
643395	4	4	4	4	4	4	4
643457	6	6	5	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	SEX RATIO (MALES)	NUMBER OF PUPS		LACTATION INDEX
		% BORN ALIVE	0-4 DAY VIABILITY	
643399	0.43	100.0	100.0	100.0
643334	0.67	100.0	100.0	100.0
643464	0.36	100.0	100.0	100.0
643369	0.39	100.0	100.0	100.0
643490	0.71	100.0	100.0	100.0
643342	0.50	100.0	100.0	100.0
643438	0.43	100.0	92.9	100.0
643445 ^a	-	-	-	-
643418	0.53	100.0	86.7	100.0
643325	0.73	100.0	100.0	100.0
643479	0.14	100.0	100.0	100.0
643403 ^a	-	-	-	-
643376	0.73	93.3	100.0	100.0
643422 ^a	-	-	-	-
643452	0.58	100.0	100.0	100.0
643475	0.00	100.0	100.0	100.0
643372	0.59	100.0	100.0	100.0
643400	0.60	93.3	85.7	100.0
643395	0.50	100.0	100.0	100.0
643457	0.63	100.0	93.8	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF MALE PUPS		
	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643399	100.0	100.0	100.0
643334	100.0	100.0	100.0
643464	100.0	100.0	100.0
643369	100.0	100.0	100.0
643490	100.0	100.0	100.0
643342	100.0	100.0	100.0
643438	100.0	100.0	100.0
643445 ^a	-	-	-
643418	100.0	87.5	100.0
643325	100.0	100.0	100.0
643479	100.0	100.0	100.0
643403 ^a	-	-	-
643376	90.9	100.0	100.0
643422 ^a	-	-	-
643452	100.0	100.0	100.0
643475	-	-	-
643372	100.0	100.0	100.0
643400	88.9	100.0	100.0
643395	100.0	100.0	100.0
643457	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

NUMBER OF FEMALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643399	100.0	100.0	100.0
643334	100.0	100.0	100.0
643464	100.0	100.0	100.0
643369	100.0	100.0	100.0
643490	100.0	100.0	100.0
643342	100.0	100.0	100.0
643438	100.0	87.5	100.0
643445 ^a	-	-	-
643418	100.0	85.7	100.0
643325	100.0	100.0	100.0
643479	100.0	100.0	100.0
643403 ^a	-	-	-
643376	100.0	100.0	100.0
643422 ^a	-	-	-
643452	100.0	100.0	100.0
643475	100.0	100.0	100.0
643372	100.0	100.0	100.0
643400	100.0	66.7	100.0
643395	100.0	100.0	100.0
643457	100.0	83.3	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF PUPS						
	BORN	BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
643320	6	4	4	4	4	4	4
643488 ^a	-	-	-	-	-	-	-
643428	14	14	14	8	8	8	8
643439	14	10	10	8	8	8	8
643353	9	9	9	8	8	8	8
643385 ^a	-	-	-	-	-	-	-
643339	15	15	15	8	8	8	8
643473 ^a	-	-	-	-	-	-	-
643337	15	15	15	8	8	8	8
643416	6	6	5	5	5	5	5
643407	16	16	0	0	0	0	0
643357 ^a	-	-	-	-	-	-	-
643331	9	0	0	0	0	0	0
643427	14	14	14	8	8	8	8
643470 ^a	-	-	-	-	-	-	-
643434	16	16	16	8	8	8	8
643349	18	18	17	8	8	8	8
643454 ^b	-	-	-	-	-	-	-
643333	7	7	7	7	7	7	7
643460	14	14	14	8	8	8	8

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF MALE PUPS					
		BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
643320	3	2	2	2	2	2	2
643488 ^a	-	-	-	-	-	-	-
643428	7	7	7	4	4	4	4
643439	9	7	7	5	5	5	5
643353	5	5	5	4	4	4	4
643385 ^a	-	-	-	-	-	-	-
643339	6	6	6	4	4	4	4
643473 ^a	-	-	-	-	-	-	-
643337	8	8	8	4	4	4	4
643416	5	5	4	4	4	4	4
643407	7	7	0	0	0	0	0
643357 ^a	-	-	-	-	-	-	-
643331	4	0	0	0	0	0	0
643427	5	5	5	4	4	4	4
643470 ^a	-	-	-	-	-	-	-
643434	6	6	6	4	4	4	4
643349	7	7	6	4	4	4	4
643454 ^b	-	-	-	-	-	-	-
643333 ^e	3 ^e	3 ^e	3	3	3	3	3
643460	7	7	7	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF FEMALE PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
643320	3	2	2	2	2	2	2
643488 ^a	-	-	-	-	-	-	-
643428	7	7	7	4	4	4	4
643439	5	3	3	3	3	3	3
643353	4	4	4	4	4	4	4
643385 ^a	-	-	-	-	-	-	-
643339	9	9	9	4	4	4	4
643473 ^a	-	-	-	-	-	-	-
643337	7	7	7	4	4	4	4
643416	1	1	1	1	1	1	1
643407	9	9	0	0	0	0	0
643357 ^a	-	-	-	-	-	-	-
643331	5	0	0	0	0	0	0
643427	9	9	9	4	4	4	4
643470 ^a	-	-	-	-	-	-	-
643434	10	10	10	4	4	4	4
643349	11	11	11	4	4	4	4
643454 ^b	-	-	-	-	-	-	-
643333 ^e	4 ^e	4 ^e	4	4	4	4	4
643460	7	7	7	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

NUMBER OF PUPS				LACTATION
ANIMAL NUMBER	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	INDEX
643320	0.50	66.7	100.0	100.0
643488 ^a	-	-	-	-
643428	0.50	100.0	100.0	100.0
643439	0.64	71.4	100.0	100.0
643353	0.56	100.0	100.0	100.0
643385 ^a	-	-	-	-
643339	0.40	100.0	100.0	100.0
643473 ^a	-	-	-	-
643337	0.53	100.0	100.0	100.0
643416	0.83	100.0	83.3	100.0
643407	0.44	100.0	0.0	-
643357 ^a	-	-	-	-
643331	0.44	0.0	-	-
643427	0.36	100.0	100.0	100.0
643470 ^a	-	-	-	-
643434	0.38	100.0	100.0	100.0
643349	0.39	100.0	94.4	100.0
643454 ^b	-	-	-	-
643333	0.43	100.0	100.0	100.0
643460	0.50	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

NUMBER OF MALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643320	66.7	100.0	100.0
643488 ^a	-	-	-
643428	100.0	100.0	100.0
643439	77.8	100.0	100.0
643353	100.0	100.0	100.0
643385 ^a	-	-	-
643339	100.0	100.0	100.0
643473 ^a	-	-	-
643337	100.0	100.0	100.0
643416	100.0	80.0	100.0
643407	100.0	0.0	-
643357 ^a	-	-	-
643331	0.0	-	-
643427	100.0	100.0	100.0
643470 ^a	-	-	-
643434	100.0	100.0	100.0
643349	100.0	85.7	100.0
643454 ^b	-	-	-
643333	100.0	100.0	100.0
643460	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

NUMBER OF FEMALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643320	66.7	100.0	100.0
643488 ^a	-	-	-
643428	100.0	100.0	100.0
643439	60.0	100.0	100.0
643353	100.0	100.0	100.0
643385 ^a	-	-	-
643339	100.0	100.0	100.0
643473 ^a	-	-	-
643337	100.0	100.0	100.0
643416	100.0	100.0	100.0
643407	100.0	0.0	-
643357 ^a	-	-	-
643331	0.0	-	-
643427	100.0	100.0	100.0
643470 ^a	-	-	-
643434	100.0	100.0	100.0
643349	100.0	100.0	100.0
643454 ^b	-	-	-
643333	100.0	100.0	100.0
643460	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF PUPS					
		BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
643467	13	13	13	8	8	8	8
643443	12	12	12	8	8	8	8
643417	10	10	10	8	8	8	8
643413	12	12	12	8	8	8	8
643338	14	14	14	8	8	8	8
643335	14	14	14	8	8	8	8
643468	14	14	14	8	8	8	8
643440	18	18	18	8	8	8	8
643430 ^a	-	-	-	-	-	-	-
643431 ^a	-	-	-	-	-	-	-
643326	14	13	12	8	8	8	8
643365	9	8	8	8	8	8	8
643375	5	1	1	1	0	0	0
643328	11	11	8	8	8	8	8
643348 ^a	-	-	-	-	-	-	-
643346 ^c	-	-	-	-	-	-	-
643449	17	17	17	8	8	8	8
643429 ^{d,e}	16	0	-	-	-	-	-
643424 ^a	-	-	-	-	-	-	-

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

NUMBER OF MALE PUPS							
ANIMAL NUMBER	BORN	BORN	PRECULLING	POSTCULLING		DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4	DAY 7		
643467	8	8	8	4	4	4	4
643443	7	7	7	4	4	4	4
643417	6	6	6	4	4	4	4
643413	7	7	7	4	4	4	4
643338	8	8	8	4	4	4	4
643335	7	7	7	4	4	4	4
643468	9	9	9	4	4	4	4
643440	9	9	9	4	4	4	4
643430 ^a	-	-	-	-	-	-	-
643431 ^a	-	-	-	-	-	-	-
643326	8	7	6	4	4	4	4
643365	4	3	3	3	3	3	3
643375	3	0	0	0	0	0	0
643328	6	6	4	4	4	4	4
643348 ^a	-	-	-	-	-	-	-
643346 ^c	-	-	-	-	-	-	-
643449	10	10	10	4	4	4	4
643429 ^d	0	0	-	-	-	-	-
643424 ^a	-	-	-	-	-	-	-

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF FEMALE PUPS						
	BORN	BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
643467	5	5	5	4	4	4	4
643443	5	5	5	4	4	4	4
643417	4	4	4	4	4	4	4
643413	5	5	5	4	4	4	4
643338	6	6	6	4	4	4	4
643335	7	7	7	4	4	4	4
643468	5	5	5	4	4	4	4
643440	9	9	9	4	4	4	4
643430 ^a	-	-	-	-	-	-	-
643431 ^a	-	-	-	-	-	-	-
643326	6	6	6	4	4	4	4
643365	5	5	5	5	5	5	5
643375	2	1	1	1	0	0	0
643328	5	5	4	4	4	4	4
643348 ^a	-	-	-	-	-	-	-
643346 ^c	-	-	-	-	-	-	-
643449	7	7	7	4	4	4	4
643429 ^d	3	0	-	-	-	-	-
643424 ^a	-	-	-	-	-	-	-

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

NUMBER OF PUPS				LACTATION
ANIMAL NUMBER	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	INDEX
643467	0.62	100.0	100.0	100.0
643443	0.58	100.0	100.0	100.0
643417	0.60	100.0	100.0	100.0
643413	0.58	100.0	100.0	100.0
643338	0.57	100.0	100.0	100.0
643335	0.50	100.0	100.0	100.0
643468	0.64	100.0	100.0	100.0
643440	0.50	100.0	100.0	100.0
643430 ^a	-	-	-	-
643431 ^a	-	-	-	-
643326	0.57	92.9	92.3	100.0
643365	0.44	88.9	100.0	100.0
643375	0.60	20.0	100.0	0.0
643328	0.55	100.0	72.7	100.0
643348 ^a	-	-	-	-
643346 ^c	-	-	-	-
643449	0.59	100.0	100.0	100.0
643429 ^d	0.00	0.0	-	-
643424 ^a	-	-	-	-

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

NUMBER OF MALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643467	100.0	100.0	100.0
643443	100.0	100.0	100.0
643417	100.0	100.0	100.0
643413	100.0	100.0	100.0
643338	100.0	100.0	100.0
643335	100.0	100.0	100.0
643468	100.0	100.0	100.0
643440	100.0	100.0	100.0
643430 ^a	-	-	-
643431 ^a	-	-	-
643326	87.5	85.7	100.0
643365	75.0	100.0	100.0
643375	0.0	-	-
643328	100.0	66.7	100.0
643348 ^a	-	-	-
643346 ^c	-	-	-
643449	100.0	100.0	100.0
643429 ^d	-	-	-
643424 ^a	-	-	-

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

NUMBER OF FEMALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
643467	100.0	100.0	100.0
643443	100.0	100.0	100.0
643417	100.0	100.0	100.0
643413	100.0	100.0	100.0
643338	100.0	100.0	100.0
643335	100.0	100.0	100.0
643468	100.0	100.0	100.0
643440	100.0	100.0	100.0
643430 ^a	-	-	-
643431 ^a	-	-	-
643326	100.0	100.0	100.0
643365	100.0	100.0	100.0
643375	50.0	100.0	0.0
643328	100.0	80.0	100.0
643348 ^a	-	-	-
643346 ^c	-	-	-
643449	100.0	100.0	100.0
643429 ^d	0.0	-	-
643424 ^a	-	-	-

APPENDIX GG
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL PUP WEIGHTS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL PUP WEIGHTS: F₁ GENERATION

EXPLANATORY NOTES

Footnotes:

- a* No litter delivered.
- b* Two pups were missexed; data excluded from male and female mean pup weights.
- c* One pup was missexed; data excluded from male and female mean pup weights.
- d* No male pups born.
- e* No live pups at birth.
- f* Found dead Day 22G (Test Day 99).
- g* Recording error, data excluded.
- h* No male pups born alive.
- i* Accidentally killed Day 14G (Test Day 91).
- j* Found dead Lactation Day 0 (Test Day 106).
- k* No live pups on Lactation Day 4.
- l* No live pups on Lactation Day 7.

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>											
		1	2	3	4	5	6	7	8	9	10	11	12
643352 ^a													
643343		7.90	7.50	7.60	7.40	7.30	7.70						
		7.40	6.90	7.00	7.00	7.40	7.40						
643459		8.20	8.30	7.20	8.00	8.40	7.70	8.10	8.20	8.30	8.70	8.10	8.10
		7.10	8.40	7.50									
643394 ^a													
643480		6.50	8.50	8.00	7.40	8.00	7.90						
		7.20	8.40	7.40	8.10	7.30	7.90	7.80	7.90	7.70			
643319 ^a													
643350 ^a													
643363		6.70	7.10	6.20	6.80	6.40	6.40	6.60					
		6.60	6.20	6.20	6.40	6.30	6.00	6.20	6.40	6.00	6.20		
643397		7.10	7.20	7.30	7.50	6.30	7.00	7.00	7.10				
		6.50	6.70	7.20	6.90	6.10	6.30	5.60	6.50				
643421		7.00	6.70	5.90	6.30	6.60	6.70						
		6.70	6.50	6.30	6.10	6.20	6.60						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>											
		1	2	3	4	5	6	7	8	9	10	11	12
643420 ^a													
643419		7.50	7.20	7.30	6.90	7.00	7.10	6.60	6.00	5.60	6.90	6.40	
		5.60	6.50	6.50	6.00	6.00							
643414 ^a													
643401		6.10	6.20	6.20	6.30	6.10	6.90	6.00	6.20	6.40	5.40	6.10	5.90
		5.30	5.80	5.60									
643455		7.00	6.50	6.60	6.90	6.60	7.10	7.00	7.20	6.90			
		6.40	5.90	6.30	6.50	6.70	5.90						
643378		8.70	9.20	7.90	7.90	8.40							
		8.10	6.60	7.90									
643393 ^a													
643447		6.60	6.30	6.20	6.50	6.70	7.00	7.20	6.50	6.60	5.50	7.10	6.50
		6.20	6.60	6.20	6.40	6.40	6.60	6.50					
643478		6.00	7.20	6.50	6.60	6.50	6.20	6.80	5.60				
		5.70	6.00	6.40	6.50	5.40	6.40	5.80					
643386		6.40	6.30	6.30	6.30	6.40	6.70	6.10	7.00	6.40	6.30		
		5.90	6.20	5.70	6.30	6.00							

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	Pup Number										
		1	2	3	4	5	6	7	8	9	10	11
643399 ^b		7.30	8.10	8.00	7.60							
		7.50	7.40	7.50	8.10	7.50	7.60	7.80	7.50	7.00	7.00	
643334		6.30	7.10	6.20	7.30	6.60	6.60	7.00	6.40	7.00	6.00	
		6.30	6.40	6.20	6.40	6.20						
643464		8.10	7.50	7.40	8.20	8.20						
		6.90	7.40	6.90	7.20	7.60	6.90	7.20	7.50	6.80		
643369		6.50	6.90	6.80	6.10	6.50	7.00	6.80				
		6.00	5.70	6.00	6.50	6.20	5.80	6.10	6.20	5.10	6.00	5.60
643490 ^c		7.00	6.90	6.60	6.40	6.90	6.80	6.60	6.70	6.00		
		6.60	6.40	5.70	6.40	6.20						
643342		7.60	7.20	7.40	6.00	6.50	6.90	6.90	6.90			
		6.20	6.90	7.30	6.30	5.90	6.70	6.60	7.10			
643438		6.20	6.30	5.80	5.80	6.00	6.00					
		6.00	6.30	5.90	6.10	5.40	5.60	6.10	6.40			
643445 ^a												
643418		6.80	6.80	6.30	4.30	6.90	6.70	6.80	6.90			
		7.00	6.10	6.60	6.60	6.30	6.00	6.40				
643325		7.20	6.60	7.50	7.10	7.10	6.90	7.00	7.50	6.90	6.70	7.30
		6.80	6.80	5.80	7.20							

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>									
		1	2	3	4	5	6	7	8	9	10 11
643479		8.30									
		7.00	7.50	7.70	7.60	7.20	7.20				
643403 ^a											
643376		6.90	6.70	7.40	6.50	7.40	6.60	7.40	6.80	6.90	7.10
		6.00	6.50	6.70	6.90						
643422 ^a											
643452		7.50	7.30	7.00	7.30	7.90	7.80	6.60			
		6.70	7.50	6.50	7.10	6.50					
643475 ^d											
		7.40	7.00								
643372		7.60	6.90	6.50	7.00	7.30	7.10	7.50	6.00	6.70	7.20
		6.60	7.00	5.80	6.20	6.60	7.10	6.90			
643400		5.60	6.00	6.00	5.50	5.90	5.90	5.50	5.70		
		5.90	5.40	5.40	5.60	4.10	5.10				
643395 ^c		7.50	6.30	6.10							
		6.40	6.50	6.60	6.90	6.20					
643457		6.30	6.00	6.40	6.00	6.10	5.90	5.80	5.90	6.50	6.90
		6.40	6.00	6.20	5.80	6.00	5.50				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643320		7.20	8.00									
		7.00	7.30									
643488 ^a												
643428		6.40	6.70	6.70	7.00	6.00	6.50	6.40				
		6.00	6.00	6.70	6.40	7.20	6.80	6.80				
643439		6.80	7.00	6.10	5.70	6.40	6.90	6.80				
		6.70	5.50	5.30								
643353		9.10	7.50	8.90	8.30	8.30						
		7.50	8.40	7.40	7.10							
643385 ^a												
643339		7.40	6.80	6.50	6.30	6.20	6.70					
		6.90	6.50	6.30	6.70	6.40	6.20	6.20	6.50	5.80		
643473 ^a												
643337		6.40	6.20	6.60	6.80	6.40	7.20	6.60	7.20			
		6.50	5.50	6.40	6.50	6.50	6.10	5.20				
643416		7.00	6.20	7.10	7.60	7.00						
		6.00										

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643407		5.70	5.30	6.50	5.70	6.30	5.70	5.70				
		5.00	4.50	5.40	4.90	5.20	5.20	6.00	6.10	5.40		
643357 ^a												
643331 ^e												
643427		7.70	7.10	7.10	6.70	7.30						
		6.80	6.70	6.70	7.80	7.00	7.00	7.10	7.10	7.10		
643470 ^a												
643434		6.70	5.70	6.50	6.50	5.60	6.50					
		5.50	6.00	5.50	6.20	5.70	6.20	6.70	6.50	5.80	5.90	
643349		6.50	5.90	6.20	6.30	6.40	6.30	6.30				
		6.20	6.10	6.10	6.00	5.60	6.70	6.00	5.60	6.20	6.40	6.00
643454 ^f												
643333 ^g												
643460		8.20	8.20	7.60	8.70	8.20	8.20	7.30				
		7.60	7.50	7.20	7.70	7.30	7.70	7.10				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>									
		1	2	3	4	5	6	7	8	9	10
643467		7.20	6.60	7.00	7.30	7.40	7.10	7.10	7.50		
		6.90	6.90	6.80	6.30	7.00					
643443		7.00	6.20	7.20	7.20	6.40	7.10	7.10			
		6.80	6.60	6.70	6.00	6.70					
643417		6.30	6.10	8.00	8.10	5.90	6.00				
		7.50	5.40	5.70	7.40						
643413		6.80	7.00	6.10	7.20	7.30	6.70	5.30			
		5.30	6.40	6.70	6.80	5.90					
643338		6.80	6.30	6.90	6.90	6.60	7.40	6.60	6.80		
		6.60	5.50	6.20	6.80	5.70	6.80				
643335		6.90	6.80	6.30	7.30	6.60	6.50	6.80			
		6.00	6.10	6.50	6.40	5.90	5.40	5.90			
643468		7.80	7.50	7.80	7.80	6.30	7.60	6.80	7.10	7.60	
		7.50	6.80	7.60	6.50	7.50					
643440		6.30	6.60	6.40	6.30	6.30	6.80	6.10	7.00	6.10	
		6.00	6.10	6.10	5.80	5.80	5.60	6.50	6.60	5.60	
643430 ^a											
643431 ^a											

Individual Pup Weights (grams): F₁ Generation
Lactation Day 0

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>									
		1	2	3	4	5	6	7	8	9	10
643326		5.70	6.60	6.20	6.90	6.50	6.50	6.20			
		6.30	6.50	6.10	5.50	6.30	6.00				
643365		6.90	7.60	7.90							
		7.00	6.50	7.00	7.20	7.50					
643375 ^h		5.30									
643328		5.80	5.30	6.00	4.90	5.20	5.50				
		5.30	5.60	5.50	5.20	5.00					
643348 ^a											
643346 ⁱ											
643449		6.40	6.80	6.20	6.70	6.80	6.10	5.70	6.50	5.80	6.10
		5.70	5.70	6.20	5.90	6.10	5.60	6.20			
643429 ^j											
643424 ^a											

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>											
		1	2	3	4	5	6	7	8	9	10	11	12
643352 ^a													
643343		12.10	13.00	12.70	12.30	12.20	12.60						
		12.10	11.90	12.00	12.10	11.10	12.10						
643459		11.10	12.30	10.90	13.80	13.50	14.20	12.10	13.00	12.70	13.80	13.60	13.30
		12.30	10.10	13.20									
643394 ^a													
643480		14.60	14.20	13.30	11.70	13.90	12.90						
		13.40	14.30	12.70	12.50	13.20	12.30	12.20	12.40	12.40			
643319 ^a													
643350 ^a													
643363		10.20	10.90	10.20	11.10	11.40	12.70	10.70					
		10.90	10.40	10.30	9.50	10.40	10.40	11.00	9.90	9.20	10.90		
643397		10.60	12.00	11.60	12.80	11.90	11.70	10.40	11.90				
		9.20	10.90	11.50	11.30	11.40	10.50	9.70	10.80				
643421		11.20	9.20	11.20	8.60	9.80	11.60						
		9.10	9.90	10.90	10.20	10.20	10.10						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	Pup Number											
		1	2	3	4	5	6	7	8	9	10	11	12
643420 ^a													
643419		12.70	12.50	11.60	9.70	10.60	12.80	10.60	9.80	12.10	10.80	9.90	
		11.50	11.40	11.10	11.20	9.80							
643414 ^a													
643401		10.10	10.30	10.00	11.00	10.10	9.70	9.80	10.00	9.60	10.20	10.70	9.70
		9.00	9.10	8.40									
643455		10.10	9.80	10.50	10.90	11.50	11.30	11.60	10.60	10.30			
		9.30	10.30	9.70	9.70	10.60	10.30						
643378		14.10	15.50	13.40	16.60	14.70							
		15.50	12.80	15.70									
643393 ^a													
643447		10.70	10.80	9.90	9.60	9.50	9.70	6.30	11.00	9.90	11.00	10.90	9.90
		9.50	10.80	9.80	9.40	9.90	10.00	9.80					
643478		11.70	11.20	11.40	10.40	11.90	10.90	11.90	11.30				
		10.80	10.10	10.00	10.50	10.50	10.30	11.60					
643386		11.20	10.40	10.40	11.60	10.50	10.90	11.10	9.80	10.20	9.40		
		9.50	10.00	9.60	10.50	9.60							

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

GROUP: IV-0

DOSE: 25 MG/KG/DAY

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643399		13.50	13.80	12.40	12.40	12.60	12.10					
		11.20	12.40	12.30	12.60	11.80	12.90	11.60	11.50			
643334		10.70	10.00	10.00	10.70	10.80	11.30	11.00	10.90	10.30	10.80	
		10.00	10.80	10.20	9.70	10.00						
643464		13.20	13.90	12.20	13.20	12.50						
		13.00	11.70	11.80	11.80	12.60	11.80	12.00	11.90	11.50		
643369		10.20	10.70	9.40	9.70	9.90	11.50	9.80				
		9.50	8.50	9.40	9.10	6.90	11.20	10.20	10.20	9.40	10.20	10.50
643490		9.90	10.10	9.90	8.70	10.50	9.40	10.10	9.70	9.80	10.20	
		9.00	8.00	8.30	8.30							
643342		13.00	11.20	10.80	10.20	10.00	12.60	12.50	12.10			
		12.10	11.40	12.00	10.40	11.80	10.50	11.70	11.20			
643438		10.00	10.20	11.00	10.90	9.60	10.50					
		9.90	10.10	10.80	9.90	10.50	9.80	10.30				
643445 ^a												
643418		11.70	11.30	11.00	10.80	11.20	11.60	6.10				
		11.10	11.00	10.10	11.20	11.70	10.60					
643325		11.40	13.50	12.30	13.00	12.80	13.60	12.60	13.20	12.80	12.90	12.80
		12.90	11.40	12.30	11.90							

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643479		15.40										
		12.70	14.50	13.70	13.70	14.40	14.20					
643403 ^a												
643376		10.40	11.40	11.10	10.50	10.50	10.80	11.10	9.80	9.70	11.70	
		9.50	10.50	10.00	10.10							
643422 ^a												
643452		12.40	12.40	11.80	11.50	12.70	12.30	11.10				
		11.60	12.70	11.00	11.70	11.70						
643475 ^d												
		15.10	13.50									
643372		10.10	10.20	11.10	11.10	10.40	10.00	12.20	11.00	11.00	9.60	
		10.30	10.90	10.10	10.90	9.20	9.50	8.60				
643400		7.70	8.70	7.10	9.70	9.00	9.30	8.60	7.90			
		8.60	8.00	8.10	7.80							
643395		12.60	13.80	13.40	13.00							
		13.20	13.20	14.40	12.90							
643457		11.70	12.00	11.10	12.60	11.30	11.20	11.60	10.80	10.50	11.50	
		11.00	10.30	10.50	11.20	11.70						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643320		13.50	15.10									
		14.10	14.00									
643488 ^a												
643428		11.20	11.00	10.90	9.90	10.40	10.70	10.20				
		9.10	10.50	10.60	11.10	9.10	11.00	10.20				
643439		10.20	13.60	12.40	13.30	10.20	13.60	12.30				
		12.00	13.30	10.40								
643353		14.40	16.70	14.70	16.50	15.80						
		10.80	13.70	15.40	14.60							
643385 ^a												
643339		10.50	10.60	11.70	11.20	11.30	10.40					
		11.00	11.10	9.60	10.30	8.40	9.90	11.20	10.60	10.90		
643473 ^a												
643337		11.00	11.40	12.70	11.90	12.00	11.50	12.50	11.10			
		10.60	11.40	12.00	10.70	11.70	8.90	11.50				
643416		13.30	13.40	13.90	13.80							
		10.70										

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>										
		1	2	3	4	5	6	7	8	9	10	11
643407 ^k												
643357 ^a												
643331 ^e												
643427		12.50	11.70	11.00	12.10	11.50						
		11.90	11.30	11.60	11.90	13.10	11.70	11.70	11.40	12.00		
643470 ^a												
643434		9.90	8.90	10.00	10.30	9.40	8.80					
		8.50	9.50	6.90	10.80	9.10	7.10	8.80	8.70	9.80	9.00	
643349		10.90	10.10	10.20	10.40	9.80	8.60					
		9.00	10.60	8.30	10.00	8.40	10.50	8.90	9.00	9.80	8.90	8.10
643454 ^f												
643333		15.60	14.60	13.80								
		14.80	13.40	14.00	13.50							
643460		12.90	12.40	12.20	11.80	12.90	12.80	12.60				
		12.10	12.20	11.30	12.40	12.00	12.20	11.90				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	Pup Number									
		1	2	3	4	5	6	7	8	9	10
643467		10.00	10.70	9.90	9.10	8.60	7.90	9.70	8.60		
		8.50	8.30	10.30	8.80	10.00					
643443		11.20	12.10	11.90	11.90	12.80	12.40	13.30			
		12.30	11.00	12.30	12.00	11.60					
643417		9.50	13.80	9.30	7.20	9.40	10.70				
		9.50	6.80	8.30	11.80						
643413		10.80	12.70	11.90	12.70	9.20	12.30	10.90			
		9.40	11.30	10.70	11.40	11.60					
643338		11.40	12.00	11.30	11.30	11.70	10.40	11.00	10.70		
		11.10	11.60	11.20	11.50	9.80	9.30				
643335		10.40	10.20	9.20	11.70	11.40	11.00	12.10			
		10.40	8.80	8.40	10.50	9.60	10.50	10.10			
643468		11.80	12.20	10.20	10.40	12.50	11.70	9.60	8.20	10.80	
		9.00	9.60	11.40	11.20	11.00					
643440		11.60	9.90	10.30	11.20	10.00	10.90	10.30	10.80	11.10	
		9.00	9.90	10.60	10.50	9.70	9.00	10.30	11.00	10.20	
643430 ^a											
643431 ^a											

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Preculling

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>									
		1	2	3	4	5	6	7	8	9	10
643326		11.40	11.00	10.90	11.40	9.80	10.90				
		11.70	10.10	11.10	11.30	10.50	10.30				
643365		10.80	11.10	11.30							
		9.90	9.70	11.30	10.80	10.20					
643375 ^h		4.80									
643328		10.10	11.30	11.40	7.90						
		9.80	11.70	9.20	11.40						
643348 ^a											
643346 ⁱ											
643449		11.10	12.20	10.30	11.30	9.90	9.70	8.40	10.10	9.70	8.60
		9.50	10.80	10.40	10.10	8.00	8.60	8.60			
643429 ^j											
643424 ^a											

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643352 ^a						
643343		13.00	12.30	12.20	12.60	
		12.10	11.90	12.10	12.10	
643459		12.30	13.80	13.50	14.20	12.70
		12.30	10.10	13.20		
643394 ^a						
643480		14.60	13.30	13.90	12.90	
		13.40	14.30	13.20	12.20	
643319 ^a						
643350 ^a						
643363		10.20	10.90	11.10	12.70	
		10.40	9.50	11.00	9.20	
643397		10.60	12.00	12.80	10.40	
		10.90	11.30	9.70	10.80	
643421		11.20	9.20	11.20	9.80	
		10.90	10.20	10.20	10.10	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643420 ^a						
643419		11.60	10.60	10.60	12.10	
		11.40	11.10	11.20	9.80	
643414 ^a						
643401		11.00	10.10	9.80	10.00	10.20
		9.00	9.10	8.40		
643455		10.90	11.50	11.30	11.60	
		10.30	9.70	9.70	10.60	
643378		14.10	15.50	13.40	16.60	14.70
		15.50	12.80	15.70		
643393 ^a						
643447		10.80	6.30	9.90	10.90	
		9.50	10.80	9.80	9.90	
643478		11.20	10.40	10.90	11.90	
		10.10	10.50	10.30	11.60	
643386		11.20	10.50	10.90	11.10	
		9.50	10.00	10.50	9.60	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	Pup Number				5	6
		1	2	3	4		
643399		13.80	12.40	12.60	12.10		
		12.40	12.30	12.60	11.80		
643334		10.70	10.80	11.00	10.30		
		10.80	10.20	9.70	10.00		
643464		13.90	12.20	13.20	12.50		
		11.80	12.60	12.00	11.90		
643369		10.20	10.70	9.40	11.50		
		8.50	10.20	10.20	9.40		
643490		9.90	8.70	10.50	10.20		
		9.00	8.00	8.30	8.30		
643342		10.80	10.00	12.50	12.10		
		11.40	12.00	10.50	11.70		
643438		10.20	11.00	9.60	10.50		
		10.80	9.90	10.50	9.80		
643445 ^a							
643418		11.30	10.80	11.60	6.10		
		11.00	10.10	11.20	11.70		
643325		11.40	12.80	13.60	13.20		
		12.90	11.40	12.30	11.90		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: IV-0

Dose: 50 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>					
		1	2	3	4	5	6
643479		15.40					
		12.70	14.50	13.70	13.70	14.40	14.20
643403 ^a							
643376		10.40	11.10	10.50	11.70		
		9.50	10.50	10.00	10.10		
643422 ^a							
643452		12.40	12.40	11.50	12.70		
		11.60	12.70	11.70	11.70		
643475 ^d							
		15.10	13.50				
643372		11.10	10.40	12.20	11.00		
		10.30	10.90	10.10	9.20		
643400		8.70	7.10	9.00	7.90		
		8.60	8.00	8.10	7.80		
643395		12.60	13.80	13.40	13.00		
		13.20	13.20	14.40	12.90		
643457		11.70	12.00	11.10	11.20		
		11.00	10.30	10.50	11.20		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643320		13.50	15.10			
		14.10	14.00			
643488 ^a						
643428		11.00	9.90	10.40	10.20	
		10.50	10.60	11.10	11.00	
643439		10.20	13.60	13.30	10.20	13.60
		12.00	13.30	10.40		
643353		14.40	16.70	16.50	15.80	
		10.80	13.70	15.40	14.60	
643385 ^a						
643339		10.50	10.60	11.20	10.40	
		11.00	9.60	9.90	11.20	
643473 ^a						
643337		12.70	11.90	11.50	12.50	
		12.00	11.70	8.90	11.50	
643416		13.30	13.40	13.90	13.80	
		10.70				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643407 ^k						
643357 ^a						
643331 ^e						
643427		12.50	11.70	11.00	12.10	
		11.60	11.90	11.70	11.40	
643470 ^a						
643434		9.90	10.00	10.30	9.40	
		6.90	7.10	8.70	9.80	
643349		10.10	10.40	9.80	8.60	
		9.00	8.30	8.90	8.90	
643454 ^f						
643333		15.60	14.60	13.80		
		14.80	13.40	14.00	13.50	
643460		12.40	12.20	12.90	12.80	
		12.10	11.30	12.20	11.90	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643467		10.70	9.90	7.90	9.70	
		8.30	10.30	8.80	10.00	
643443		11.20	12.10	12.80	12.40	
		12.30	11.00	12.30	12.00	
643417		9.50	13.80	9.30	7.20	
		9.50	6.80	8.30	11.80	
643413		11.90	9.20	12.30	10.90	
		11.30	10.70	11.40	11.60	
643338		12.00	11.30	11.30	11.70	
		11.60	11.20	11.50	9.30	
643335		10.40	11.70	11.40	11.00	
		10.40	8.80	8.40	10.50	
643468		12.20	11.70	9.60	8.20	
		9.60	11.40	11.20	11.00	
643440		9.90	10.30	10.00	10.80	
		10.60	10.50	9.70	11.00	
643430 ^a						
643431 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 4 Postculling

Group: VIII-0

Dose: 1000 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643326		11.00	10.90	11.40	10.90	
		11.70	11.30	10.50	10.30	
643365		10.80	11.10	11.30		
		9.90	9.70	11.30	10.80	10.20
643375 ^h		4.80				
643328		10.10	11.30	11.40	7.90	
		9.80	11.70	9.20	11.40	
643348 ^a						
643346 ⁱ						
643449		12.20	11.30	9.90	10.10	
		10.40	10.10	8.00	8.60	
643429 ^j						
643424 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643352 ^a						
643343		19.40	18.70	19.60	19.70	
		18.40	19.00	18.70	18.80	
643459		22.70	21.50	22.70	22.40	20.30
		17.10	20.70	19.00		
643394 ^a						
643480		21.20	23.10	20.20	22.90	
		19.60	21.40	22.20	20.10	
643319 ^a						
643350 ^a						
643363		19.40	16.90	20.70	18.90	
		17.10	16.30	18.20	18.50	
643397		17.60	20.00	22.10	18.30	
		16.90	19.40	18.80	18.10	
643421		16.00	13.70	14.40	16.90	
		14.50	15.00	15.10	15.80	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643420 ^a						
643419		19.50	17.90	20.00	18.20	
		16.20	19.00	18.40	18.70	
643414 ^a						
643401		17.00	17.50	17.00	17.40	16.60
		14.80	15.50	15.90		
643455		16.90	17.40	17.20	16.50	
		14.70	15.70	17.30	15.10	
643378		19.40	20.50	19.60	23.00	19.70
		18.40	22.00	22.00		
643393 ^a						
643447		18.50	18.70	18.30	15.70	
		17.20	18.70	15.80	17.20	
643478		16.70	17.10	17.50	15.60	
		15.80	16.40	15.70	15.20	
643386		18.80	19.00	19.60	18.80	
		16.80	17.40	15.40	17.90	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	Pup Number					
		1	2	3	4	5	6
643399		19.70	21.30	19.50	19.00		
		19.30	19.70	19.20	18.80		
643334		17.60	18.00	19.30	19.40		
		16.70	14.40	18.90	15.80		
643464		16.90	17.30	19.10	18.00		
		16.50	16.50	16.30	17.10		
643369		15.90	17.70	16.30	17.50		
		15.00	14.60	16.40	16.40		
643490		15.20	17.00	17.20	16.90		
		14.90	15.60	16.00	15.70		
643342		16.80	18.00	17.90	19.30		
		18.20	19.40	18.80	18.30		
643438		16.40	17.50	16.40	18.40		
		17.10	15.80	16.70	17.40		
643445 ^a							
643418		9.20	19.30	17.80	18.80		
		17.20	17.70	18.80	18.20		
643325		19.00	22.30	20.70	22.80		
		21.70	19.60	21.90	19.70		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>					
		1	2	3	4	5	6
643479		22.50					
		21.00	21.40	19.10	18.10	19.60	20.50
643403 ^a							
643376		17.70	19.20	15.60	16.80		
		15.00	16.60	15.10	17.20		
643422 ^a							
643452		19.40	20.10	19.60	18.00		
		18.30	19.30	18.40	18.20		
643475 ^d							
		22.50	20.60				
643372		17.90	17.00	18.80	17.90		
		17.10	17.00	15.50	15.80		
643400		12.50	14.40	13.00	10.60		
		13.40	11.90	12.80	12.20		
643395		19.40	20.90	20.40	21.20		
		19.90	19.00	18.70	20.40		
643457		19.90	20.80	19.00	17.90		
		18.20	18.10	17.80	17.30		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643320		22.50	21.20			
		21.30	22.60			
643488 ^a						
643428		17.10	17.40	18.10	17.80	
		17.70	17.80	18.50	16.90	
643439		20.50	16.90	20.80	16.90	20.00
		17.10	18.00	20.00		
643353		23.50	23.30	21.30	23.50	
		20.80	22.40	20.50	16.20	
643385 ^a						
643339		17.70	18.10	17.10	17.00	
		17.50	16.00	17.50	16.30	
643473 ^a						
643337		20.30	19.40	21.70	20.10	
		18.50	19.50	19.40	15.70	
643416		17.70	18.10	19.20	19.00	
		15.00				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643407 ^k						
643357 ^a						
643331 ^e						
643427		19.80	17.80	19.50	19.20	
		19.10	19.00	19.30	19.30	
643470 ^a						
643434		17.10	14.90	15.90	16.90	
		14.10	15.80	11.40	10.70	
643349		16.60	17.60	17.60	15.40	
		15.40	13.70	14.80	14.00	
643454 ^f						
643333		20.90	22.70	20.20		
		20.60	19.70	21.30	19.50	
643460		16.20	16.00	15.90	15.50	
		14.30	15.00	15.10	13.90	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643467		12.40	10.20	13.50	13.80	
		11.50	13.60	15.60	11.30	
643443		18.80	20.10	19.60	20.20	
		18.10	19.00	19.50	19.50	
643417		20.00	12.90	9.60	14.90	
		15.00	17.20	11.80	9.80	
643413		13.10	18.10	16.20	18.40	
		16.80	16.50	16.90	15.20	
643338		16.50	15.90	15.80	16.30	
		16.70	16.00	14.00	16.50	
643335		19.50	19.60	18.30	17.80	
		17.20	15.40	17.60	15.20	
643468		13.80	11.80	17.10	17.90	
		16.40	16.10	12.00	17.20	
643440		12.20	11.80	12.80	11.70	
		12.70	12.30	10.80	11.90	
643430 ^a						
643431 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 7

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643326		14.80	17.10	18.40	16.90	
		17.70	16.70	17.80	15.80	
643365		14.90	14.10	14.80		
		12.60	13.90	12.90	13.60	14.60
643375 ^{h,1}						
643328		12.20	15.00	16.20	17.30	
		17.60	16.00	17.30	14.60	
643348 ^a						
643346 ⁱ						
643449		15.20	20.30	17.60	15.80	
		15.80	17.10	15.30	13.50	
643429 ^j						
643424 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643352 ^a						
643343		37.90	40.90	39.20	38.70	
		36.00	38.10	37.20	37.30	
643459		43.70	43.10	44.50	40.60	46.10
		36.00	40.60	40.50		
643394 ^a						
643480		43.30	45.00	43.70	46.30	
		44.50	41.90	43.30	43.90	
643319 ^a						
643350 ^a						
643363		38.20	42.30	43.10	41.00	
		39.60	38.80	36.80	40.10	
643397		41.00	33.30	34.60	37.20	
		34.80	35.80	33.10	35.20	
643421		30.60	33.30	30.30	34.80	
		31.60	30.60	32.10	32.10	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643420 ^a						
643419		43.30	42.10	42.90	41.60	
		38.50	41.10	40.70	41.30	
643414 ^a						
643401		35.70	35.70	36.30	37.40	35.30
		35.00	31.30	33.80		
643455		36.20	35.30	35.30	30.50	
		32.30	30.60	34.50	35.20	
643378		36.70	38.90	38.10	37.30	40.60
		40.10	39.60	33.60		
643393 ^a						
643447		39.50	37.50	37.30	34.30	
		34.00	36.40	35.50	38.00	
643478		36.90	37.60	38.80	38.70	
		37.20	36.50	38.80	37.40	
643386		39.80	39.20	40.20	40.90	
		37.10	39.60	37.50	37.40	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: IV-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number					
		1	2	3	4	5	6
643399		39.90	39.00	39.10	37.20		
		37.40	37.30	38.70	36.90		
643334		38.30	38.50	37.60	38.20		
		37.10	34.60	38.00	35.30		
643464		38.30	40.10	38.20	41.10		
		37.50	38.20	37.90	37.40		
643369		36.00	37.90	35.70	38.30		
		35.30	37.20	34.40	36.20		
643490		35.10	37.70	34.30	36.50		
		33.80	34.80	33.70	36.30		
643342		39.30	41.70	38.20	42.70		
		39.80	38.90	40.30	39.10		
643438		34.90	33.80	37.70	36.90		
		37.10	34.40	36.50	32.90		
643445 ^a							
643418		39.00	37.80	38.30	25.10		
		37.60	36.10	37.90	38.10		
643325		47.10	42.80	46.90	44.90		
		43.20	45.20	46.40	40.60		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: IV-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>					
		1	2	3	4	5	6
643479		39.90					
		35.10	35.90	40.20	36.70	31.30	34.40
643403 ^a							
643376		34.70	34.40	33.70	39.90		
		31.20	31.00	35.80	32.20		
643422 ^a							
643452		36.30	38.00	36.70	36.90		
		36.40	37.00	35.80	34.60		
643475 ^d							
		39.80	38.50				
643372		38.40	39.60	37.00	37.00		
		35.40	35.80	33.90	32.60		
643400		32.20	29.90	27.30	30.70		
		32.20	30.00	28.90	29.50		
643395		37.50	36.80	36.50	38.20		
		37.30	35.30	37.00	36.10		
643457		40.10	40.80	39.30	36.30		
		38.30	38.60	38.70	37.80		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643320		44.60	43.00			
		43.90	41.20			
643488 ^a						
643428		36.10	36.40	33.60	34.50	
		36.20	34.40	32.70	33.60	
643439		36.40	37.80	38.70	32.50	38.80
		38.80	35.00	34.80		
643353		40.20	38.40	39.60	39.80	
		35.40	36.20	31.40	38.30	
643385 ^a						
643339		36.10	38.00	38.90	37.10	
		39.50	34.20	35.50	35.80	
643473 ^a						
643337		38.40	41.30	38.80	40.70	
		38.50	37.70	39.60	33.20	
643416		36.20	36.10	35.30	38.10	
		32.40				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643407 ^k						
643357 ^a						
643331 ^e						
643427		35.70	39.90	36.20	36.80	
		36.50	37.40	38.20	36.70	
643470 ^a						
643434		31.60	34.40	37.10	34.30	
		23.50	27.90	30.30	32.60	
643349		28.30	34.30	34.40	32.00	
		30.10	32.20	31.10	29.90	
643454 ^f						
643333		36.30	38.00	40.30		
		38.80	35.80	35.70	35.60	
643460		33.40	34.90	33.20	34.90	
		32.10	32.20	32.50	33.40	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: VIII-0

Dose: 1000 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643467		30.40	25.60	16.70	24.30	
		25.50	34.10	30.50	23.60	
643443		35.10	34.00	35.30	34.80	
		32.20	34.90	32.50	33.80	
643417		34.40	26.90	20.50	28.20	
		31.50	19.60	27.90	24.90	
643413		28.90	25.90	28.00	22.30	
		25.80	26.90	26.60	26.30	
643338		30.70	33.00	31.00	33.10	
		31.60	29.80	32.20	31.50	
643335		29.60	31.30	31.20	29.90	
		29.60	27.10	29.00	26.80	
643468		32.80	37.70	28.10	35.70	
		36.90	35.20	33.60	31.10	
643440		28.10	26.90	26.00	30.10	
		28.50	25.50	29.00	29.70	
643430 ^a						
643431 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 14

Group: VIII-0

Dose: 1000 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643326		33.40	32.50	32.50	30.20	
		30.70	31.70	33.10	31.80	
643365		30.00	29.30	23.30		
		28.00	29.00	28.20	26.90	26.90
643375 ^{h, l}						
643328		20.80	27.40	24.10	25.20	
		21.90	23.60	26.40	25.60	
643348 ^a						
643346 ⁱ						
643449		35.50	36.60	31.80	33.30	
		35.20	33.00	28.80	31.60	
643429 ^j						
643424 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643352 ^a						
643343		66.50	64.30	65.60	62.70	
		58.70	61.00	64.00	59.30	
643459		72.00	67.80	69.90	71.70	74.60
		67.40	65.60	59.10		
643394 ^a						
643480		70.90	79.00	77.40	73.20	
		72.50	72.80	71.50	67.40	
643319 ^a						
643350 ^a						
643363		67.60	68.30	66.30	73.60	
		65.30	61.80	65.20	62.00	
643397		62.20	60.10	58.10	64.60	
		55.60	57.60	57.40	55.10	
643421		45.70	47.60	44.20	49.50	
		45.30	47.70	44.10	45.90	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643420 ^a						
643419		62.50	62.30	66.30	63.70	
		66.80	58.60	63.70	60.50	
643414 ^a						
643401		57.70	61.00	56.20	57.40	58.10
		56.20	56.00	50.30		
643455		56.90	55.20	48.40	54.00	
		54.20	49.50	57.50	46.50	
643378		66.70	61.60	60.40	59.60	67.20
		65.50	54.30	63.10		
643393 ^a						
643447		58.80	62.60	56.20	59.50	
		58.60	50.70	57.50	58.40	
643478		63.80	59.00	61.30	59.70	
		58.60	61.30	63.50	58.50	
643386		66.90	67.90	66.30	63.00	
		64.40	59.70	60.60	58.30	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

GROUP: IV-0

DOSE: 25 MG/KG/DAY

Animal Number	Pup Sex	Pup Number					
		1	2	3	4	5	6
643399		59.80	65.50	65.20	67.50		
		59.40	62.60	64.90	61.40		
643334		60.30	61.90	61.30	63.20		
		61.00	61.80	56.60	58.50		
643464		70.50	66.90	67.80	68.10		
		65.20	61.80	63.70	63.90		
643369		63.30	59.50	57.20	56.40		
		56.80	54.60	55.70	56.30		
643490		55.20	65.40	53.80	58.10		
		56.40	57.20	52.70	54.50		
643342		67.50	61.10	67.80	64.50		
		61.70	61.80	61.90	65.10		
643438		54.30	63.00	56.80	62.00		
		62.00	53.90	58.50	59.10		
643445 ^a							
643418		61.60	39.30	59.40	60.20		
		57.00	56.20	56.10	59.90		
643325		68.70	77.90	70.10	72.90		
		66.40	66.60	72.30	69.00		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>					
		1	2	3	4	5	6
643479		70.90					
		60.40	69.60	60.20	66.10	61.20	60.50
643403 ^a							
643376		54.00	56.60	58.00	64.30		
		49.50	55.70	50.10	44.80		
643422 ^a							
643452		62.50	66.60	60.90	61.70		
		60.40	60.30	61.00	58.40		
643475 ^d							
		66.50	67.00				
643372		62.00	66.20	62.80	64.80		
		55.60	58.00	61.10	56.50		
643400		47.00	47.30	51.90	42.10		
		45.60	43.90	48.20	46.70		
643395		61.00	60.60	58.30	59.50		
		60.50	56.80	58.80	56.00		
643457		57.00	61.40	58.40	63.50		
		56.90	55.60	58.80	59.00		

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643320		68.50	60.50			
		60.60	65.70			
643488 ^a						
643428		58.40	57.10	58.70	52.10	
		54.00	56.70	54.20	52.10	
643439		59.00	61.40	55.10	60.40	48.20
		60.40	56.50	53.10		
643353		65.80	60.30	66.10	66.30	
		64.30	50.20	59.70	59.00	
643385 ^a						
643339		59.40	60.30	56.60	56.60	
		53.10	58.80	57.70	55.80	
643473 ^a						
643337		62.60	64.20	64.40	60.70	
		55.90	61.40	52.80	62.50	
643416		61.30	64.50	63.30	59.90	
		54.30				

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: VI-0 Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number				
		1	2	3	4	5
643407 ^k						
643357 ^a						
643331 ^e						
643427		63.10	61.70	62.40	66.00	
		60.80	57.30	57.80	60.40	
643470 ^a						
643434		59.20	50.30	56.10	53.40	
		38.90	45.30	48.00	51.50	
643349		43.90	56.30	51.60	55.80	
		46.30	48.90	51.60	49.30	
643454 ^f						
643333		58.80	66.70	63.70		
		59.60	61.60	60.10	56.10	
643460		63.20	64.90	64.50	59.60	
		55.70	57.00	56.00	60.10	

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: VIII-0

Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643467		43.70	54.00	29.80	42.60	
		45.10	43.00	54.60	58.40	
643443		38.10	39.20	35.70	41.30	
		35.60	35.10	35.70	39.70	
643417		32.00	23.00	29.00	40.00	
		33.60	22.10	30.30	27.90	
643413		31.20	39.50	37.00	40.80	
		36.10	34.20	34.60	35.80	
643338		49.60	50.30	52.80	50.70	
		50.30	46.10	51.70	47.60	
643335		54.60	50.80	56.90	50.70	
		49.00	45.50	49.00	45.20	
643468		43.40	59.10	57.80	52.40	
		60.30	52.80	55.70	45.60	
643440		45.00	46.60	53.60	48.50	
		44.60	48.90	50.70	49.00	
643430 ^a						
643431 ^a						

Individual Pup Weights (grams): F₁ Generation
Lactation Day 21

Group: VIII-0 Dose: 250 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>				
		1	2	3	4	5
643326		53.70	53.50	49.40	51.20	
		55.40	50.60	53.50	52.20	
643365		39.90	47.10	46.50		
		44.70	41.80	42.90	44.00	43.60
643375 ^{h,1}						
643328		34.60	47.50	41.00	43.40	
		45.50	39.70	45.60	40.40	
643348 ^a						
643346 ⁱ						
643449		52.40	53.10	60.40	55.70	
		47.40	58.40	54.30	51.50	
643429 ^j						
643424 ^a						

APPENDIX HH

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

EXPLANATORY NOTES

Footnotes

a No live pups born

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

GROUP: II-0 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
643343		NO ABNORMALITIES DETECTED	
643459		NO ABNORMALITIES DETECTED	
643480		NO ABNORMALITIES DETECTED	
643363		NO ABNORMALITIES DETECTED	
643397		NO ABNORMALITIES DETECTED	
643421		NO ABNORMALITIES DETECTED	
643419		NO ABNORMALITIES DETECTED	
643401		NO ABNORMALITIES DETECTED	
643455		NO ABNORMALITIES DETECTED	
643378		NO ABNORMALITIES DETECTED	
643447		NO ABNORMALITIES DETECTED	
643478		NO ABNORMALITIES DETECTED	
643386		NO ABNORMALITIES DETECTED	

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

GROUP: IV-0 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
643399			NO ABNORMALITIES DETECTED
643334			NO ABNORMALITIES DETECTED
643464			NO ABNORMALITIES DETECTED
643369			NO ABNORMALITIES DETECTED
643490			NO ABNORMALITIES DETECTED
643342			NO ABNORMALITIES DETECTED
643438			NO ABNORMALITIES DETECTED
643418			NO ABNORMALITIES DETECTED
643325			NO ABNORMALITIES DETECTED
643479			NO ABNORMALITIES DETECTED
643376			NO ABNORMALITIES DETECTED
643452			NO ABNORMALITIES DETECTED
643475			NO ABNORMALITIES DETECTED
643372			NO ABNORMALITIES DETECTED
643400			NO ABNORMALITIES DETECTED
643395			NO ABNORMALITIES DETECTED
643457			NO ABNORMALITIES DETECTED

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

GROUP: VI-0 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
643320		NO ABNORMALITIES DETECTED	
643428		NO ABNORMALITIES DETECTED	
643439		NO ABNORMALITIES DETECTED	
643353		NO ABNORMALITIES DETECTED	
643339		NO ABNORMALITIES DETECTED	
643337		NO ABNORMALITIES DETECTED	
643416		NO ABNORMALITIES DETECTED	
643407		NO ABNORMALITIES DETECTED	
643331 ^a			
643427		NO ABNORMALITIES DETECTED	
643434		NO ABNORMALITIES DETECTED	
643349		NO ABNORMALITIES DETECTED	
643333		NO ABNORMALITIES DETECTED	
643460		NO ABNORMALITIES DETECTED	

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

GROUP: VIII-0 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
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643467			NO ABNORMALITIES DETECTED
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643443			NO ABNORMALITIES DETECTED
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643417	DAY 21	3 OF 8	DISCHARGE NOSE BLACK
		2 OF 8	WEAK

LITTER SUMMARY:	3	DISCHARGE NOSE
	2	WEAK

DAY 21 PUP DATA: PUP:

a	DISCHARGE NOSE BLACK
	WEAK
b	DISCHARGE NOSE BLACK
	WEAK
c	DISCHARGE NOSE BLACK

643413	NO ABNORMALITIES DETECTED
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643338	NO ABNORMALITIES DETECTED
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643335	NO ABNORMALITIES DETECTED
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643468	NO ABNORMALITIES DETECTED
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643440	NO ABNORMALITIES DETECTED
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643326	NO ABNORMALITIES DETECTED
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643365	NO ABNORMALITIES DETECTED
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643375	NO ABNORMALITIES DETECTED
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643328	NO ABNORMALITIES DETECTED
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643449	NO ABNORMALITIES DETECTED
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643429 ^a	
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APPENDIX II

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHTS: F₁ GENERATION

EXPLANATORY NOTES

Notes

Day of weaning = Test Day 1.

a No data due to weighing error.

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ MALE RATS

GROUP: I-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647068	62.7	103.2	156.5	204.0	251.7	303.9
647069	74.6	132.2	207.8	279.5	352.7	411.7
647070	73.2	118.0	182.8	248.8	310.2	326.6
647071	73.6	130.1	201.1	264.2	336.7	333.8
647072	64.6	115.0	181.8	243.5	307.8	367.0
647073	49.5	94.7	156.0	213.7	265.6	325.4
647074	63.7	107.2	176.4	250.0	325.4	314.3
647075	58.1	98.9	154.7	215.9	257.3	323.3
647076	54.0	93.7	153.0	218.3	279.2	284.7
647077	67.2	114.4	179.9	250.6	282.6	366.5
647078	59.5	101.1	167.6	227.3	273.9	349.4
647079	59.7	95.2	158.8	228.7	302.6	325.9
647080	63.0	109.0	162.3	227.5	285.8	302.2

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ MALE RATS

GROUP: III-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647123	67.5	106.2	176.4	230.8	301.6	-a
647124	63.2	108.5	172.2	236.4	282.6	343.9
647125	68.1	103.3	158.8	213.2	278.2	304.5
647126	56.4	97.6	156.8	215.0	276.4	336.7
647127	58.1	103.5	166.5	225.8	290.2	348.4
647128	64.5	105.7	163.7	232.3	247.0	341.2
647129	62.0	102.2	167.0	234.8	260.1	283.5
647130	60.2	107.1	168.5	237.5	293.3	363.8
647131	72.9	122.8	187.5	242.4	319.2	383.2
647132	70.9	113.1	176.0	231.0	285.7	341.5
647133	64.3	104.3	165.5	224.4	280.5	302.5
647134	61.7	108.7	170.8	231.7	308.6	376.1
647135	64.8	103.4	164.4	229.1	279.2	311.9
647136	42.1	73.3	118.6	171.6	222.2	276.8
647137	59.5	95.2	145.1	207.3	261.9	324.0
647138	63.5	108.2	165.0	220.4	272.8	339.1

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ MALE RATS

GROUP: V-1

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647184	60.5	99.6	151.8	217.6	264.4	276.6
647185	52.1	92.8	150.0	212.6	279.5	298.2
647186	48.2	81.8	135.3	203.5	232.7	259.1
647187	66.3	114.4	181.3	244.6	315.5	382.7
647188	56.6	98.8	167.6	221.1	302.2	375.5
647189	60.7	106.5	168.7	231.2	267.4	299.1
647190	59.9	98.0	158.9	223.3	280.7	300.9
647191	66.0	109.8	175.1	237.6	275.2	305.1
647192	53.4	96.1	157.7	225.3	286.7	300.2
647193	55.8	94.4	150.7	210.1	274.0	300.1
647194	63.7	104.7	165.0	223.4	288.7	313.4
647195	59.6	108.8	173.0	225.2	283.9	314.5

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ MALE RATS

GROUP: VII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647230	42.6	86.3	137.5	203.2	258.8	318.3
647231	41.3	91.5	144.5	211.9	272.7	331.9
647232	40.0	96.7	170.4	224.0	344.6	417.0
647233	40.8	82.1	139.6	197.3	252.2	280.9
647234	50.7	96.4	158.8	221.1	281.3	296.9
647235	50.7	85.3	143.5	200.7	255.5	275.0
647236	52.4	87.4	143.3	209.1	259.0	318.9
647237	48.5	83.9	139.6	210.9	242.8	265.3
647238	51.2	84.8	131.4	190.5	239.8	299.5
647239	46.5	80.3	135.8	202.0	270.4	277.7
647240	43.4	80.5	133.4	187.0	245.1	313.3
647241	55.7	100.9	155.8	214.3	246.2	327.4

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ FEMALE RATS

GROUP: II-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647277	59.3	96.0	130.3	156.9	177.1	203.4
647278	59.1	103.1	139.6	160.9	182.7	201.4
647279	67.4	103.8	136.8	152.2	170.8	179.7
647280	62.0	99.6	143.7	180.4	199.8	221.4
647281	55.1	96.4	144.1	185.9	204.7	219.6
647282	45.9	84.1	132.3	163.3	192.7	212.8
647283	60.5	93.2	139.9	179.6	207.7	219.6
647284	50.3	85.0	122.5	158.2	173.2	200.7
647285	46.5	78.1	121.7	155.0	176.8	191.0
647286	63.1	95.5	137.1	181.8	210.2	211.6
647287	58.4	102.2	156.4	185.8	217.7	231.0
647288	58.5	94.0	135.0	167.0	194.6	213.7
647289	58.3	91.4	126.3	150.2	161.6	176.7

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ FEMALE RATS

GROUP: IV-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647326	61.4	91.7	138.6	161.4	186.1	-a
647327	58.5	97.0	143.9	186.5	204.9	223.5
647328	63.9	98.2	137.7	168.8	192.1	206.5
647329	56.3	96.0	146.2	181.1	209.8	228.5
647330	54.5	92.1	141.0	176.9	201.1	223.2
647331	65.1	106.5	158.4	212.3	246.4	283.9
647332	59.1	98.1	150.9	196.4	223.6	242.1
647333	59.9	99.4	145.1	180.0	191.4	203.7
647334	69.0	108.8	171.7	220.4	232.3	280.7
647335	60.5	100.3	140.9	162.9	171.7	197.7
647336	44.8	77.6	114.8	137.3	146.5	164.9
647337	58.4	95.5	137.8	171.9	195.8	222.7
647338	67.0	99.0	137.1	171.9	200.7	218.1
647339	56.5	87.9	124.0	155.7	174.7	196.8
647340	46.7	79.5	120.6	150.5	172.1	192.7
647341	56.0	86.7	123.3	151.1	180.4	196.2
647342	59.0	97.5	140.4	168.3	196.1	219.3

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ FEMALE RATS

GROUP: VI-1

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647394	65.7	101.8	143.2	167.7	193.1	213.2
647395	52.1	88.9	135.5	166.5	194.3	215.3
647396	53.1	90.3	131.5	164.1	185.0	206.8
647397	59.0	91.5	125.9	161.1	167.7	194.1
647398	55.8	96.1	138.5	177.8	211.5	235.8
647399	62.5	84.0	142.2	184.3	209.8	235.6
647400	54.3	86.5	132.0	166.2	190.3	215.2
647401	60.4	97.6	141.8	177.2	204.7	222.1
647402	51.5	87.6	130.8	170.3	200.8	219.3
647403	49.3	77.8	117.1	142.0	159.8	173.7
647404	56.1	84.3	123.9	160.1	181.8	196.9
647405	60.1	98.2	141.0	173.0	198.3	222.9

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ FEMALE RATS

GROUP: VIII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
647436	58.4	97.2	142.1	176.2	203.5	197.3
647437	39.7	88.5	124.3	157.1	190.5	194.5
647438	27.9	68.1	117.6	166.1	210.4	238.3
647439	35.8	70.4	113.2	143.3	170.6	193.8
647440	47.6	78.5	125.8	167.8	190.7	219.7
647441	45.2	76.6	123.3	162.1	189.6	209.0
647442	45.6	77.8	118.3	153.4	164.3	187.7
647443	49.0	80.2	124.3	157.1	183.4	210.1
647444	52.2	84.9	127.3	157.0	173.4	206.9
647445	43.6	69.1	115.4	158.3	186.7	217.1
647446	40.4	73.8	124.6	163.2	190.3	202.0
647447	51.5	94.5	141.4	178.9	199.1	198.8

APPENDIX JJ

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL BODY WEIGHT GAINS: F₁ GENERATION

EXPLANATORY NOTES

Notes

Day of weaning = Test Day 1.

a No data due to weighing error.

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ MALE RATS

GROUP: I-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647068	40.5	53.3	47.5	47.7	52.2	241.2
647069	57.6	75.6	71.7	73.2	59.0	337.1
647070	44.8	64.8	66.0	61.4	16.4	253.4
647071	56.5	71.0	63.1	72.5	-2.9	260.2
647072	50.4	66.8	61.7	64.3	59.2	302.4
647073	45.2	61.3	57.7	51.9	59.8	275.9
647074	43.5	69.2	73.6	75.4	-11.1	250.6
647075	40.8	55.8	61.2	41.4	66.0	265.2
647076	39.7	59.3	65.3	60.9	5.5	230.7
647077	47.2	65.5	70.7	32.0	83.9	299.3
647078	41.6	66.5	59.7	46.6	75.5	289.9
647079	35.5	63.6	69.9	73.9	23.3	266.2
647080	46.0	53.3	65.2	58.3	16.4	239.2

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ MALE RATS

GROUP: III-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647123	38.7	70.2	54.4	70.8	-a	-a
647124	45.3	63.7	64.2	46.2	61.3	280.7
647125	35.2	55.5	54.4	65.0	26.3	236.4
647126	41.2	59.2	58.2	61.4	60.3	280.3
647127	45.4	63.0	59.3	64.4	58.2	290.3
647128	41.2	58.0	68.6	14.7	94.2	276.7
647129	40.2	64.8	67.8	25.3	23.4	221.5
647130	46.9	61.4	69.0	55.8	70.5	303.6
647131	49.9	64.7	54.9	76.8	64.0	310.3
647132	42.2	62.9	55.0	54.7	55.8	270.6
647133	40.0	61.2	58.9	56.1	22.0	238.2
647134	47.0	62.1	60.9	76.9	67.5	314.4
647135	38.6	61.0	64.7	50.1	32.7	247.1
647136	31.2	45.3	53.0	50.6	54.6	234.7
647137	35.7	49.9	62.2	54.6	62.1	264.5
647138	44.7	56.8	55.4	52.4	66.3	275.6

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ MALE RATS

GROUP: V-1

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647184	39.1	52.2	65.8	46.8	12.2	216.1
647185	40.7	57.2	62.6	66.9	18.7	246.1
647186	33.6	53.5	68.2	29.2	26.4	210.9
647187	48.1	66.9	63.3	70.9	67.2	316.4
647188	42.2	68.8	53.5	81.1	73.3	318.9
647189	45.8	62.2	62.5	36.2	31.7	238.4
647190	38.1	60.9	64.4	57.4	20.2	241.0
647191	43.8	65.3	62.5	37.6	29.9	239.1
647192	42.7	61.6	67.6	61.4	13.5	246.8
647193	38.6	56.3	59.4	63.9	26.1	244.3
647194	41.0	60.3	58.4	65.3	24.7	249.7
647195	49.2	64.2	52.2	58.7	30.6	254.9

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ MALE RATS

GROUP: VII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647230	43.7	51.2	65.7	55.6	59.5	275.7
647231	50.2	53.0	67.4	60.8	59.2	290.6
647232	56.7	73.7	53.6	120.6	72.4	377.0
647233	41.3	57.5	57.7	54.9	28.7	240.1
647234	45.7	62.4	62.3	60.2	15.6	246.2
647235	34.6	58.2	57.2	54.8	19.5	224.3
647236	35.0	55.9	65.8	49.9	59.9	266.5
647237	35.4	55.7	71.3	31.9	22.5	216.8
647238	33.6	46.6	59.1	49.3	59.7	248.3
647239	33.8	55.5	66.2	68.4	7.3	231.2
647240	37.1	52.9	53.6	58.1	68.2	269.9
647241	45.2	54.9	58.5	31.9	81.2	271.7

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ FEMALE RATS

GROUP: II-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647277	36.7	34.3	26.6	20.2	26.3	144.1
647278	44.0	36.5	21.3	21.8	18.7	142.3
647279	36.4	33.0	15.4	18.6	8.9	112.3
647280	37.6	44.1	36.7	19.4	21.6	159.4
647281	41.3	47.7	41.8	18.8	14.9	164.5
647282	38.2	48.2	31.0	29.4	20.1	166.9
647283	32.7	46.7	39.7	28.1	11.9	159.1
647284	34.7	37.5	35.7	15.0	27.5	150.4
647285	31.6	43.6	33.3	21.8	14.2	144.5
647286	32.4	41.6	44.7	28.4	1.4	148.5
647287	43.8	54.2	29.4	31.9	13.3	172.6
647288	35.5	41.0	32.0	27.6	19.1	155.2
647289	33.1	34.9	23.9	11.4	15.1	118.4

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ FEMALE RATS

GROUP: IV-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647326	30.3	46.9	22.8	24.7	-a	-a
647327	38.5	46.9	42.6	18.4	18.6	165.0
647328	34.3	39.5	31.1	23.3	14.4	142.6
647329	39.7	50.2	34.9	28.7	18.7	172.2
647330	37.6	48.9	35.9	24.2	22.1	168.7
647331	41.4	51.9	53.9	34.1	37.5	218.8
647332	39.0	52.8	45.5	27.2	18.5	183.0
647333	39.5	45.7	34.9	11.4	12.3	143.8
647334	39.8	62.9	48.7	11.9	48.4	211.7
647335	39.8	40.6	22.0	8.8	26.0	137.2
647336	32.8	37.2	22.5	9.2	18.4	120.1
647337	37.1	42.3	34.1	23.9	26.9	164.3
647338	32.0	38.1	34.8	28.8	17.4	151.1
647339	31.4	36.1	31.7	19.0	22.1	140.3
647340	32.8	41.1	29.9	21.6	20.6	146.0
647341	30.7	36.6	27.8	29.3	15.8	140.2
647342	38.5	42.9	27.9	27.8	23.2	160.3

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ FEMALE RATS

GROUP: VI-1

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647394	36.1	41.4	24.5	25.4	20.1	147.5
647395	36.8	46.6	31.0	27.8	21.0	163.2
647396	37.2	41.2	32.6	20.9	21.8	153.7
647397	32.5	34.4	35.2	6.6	26.4	135.1
647398	40.3	42.4	39.3	33.7	24.3	180.0
647399	21.5	58.2	42.1	25.5	25.8	173.1
647400	32.2	45.5	34.2	24.1	24.9	160.9
647401	37.2	44.2	35.4	27.5	17.4	161.7
647402	36.1	43.2	39.5	30.5	18.5	167.8
647403	28.5	39.3	24.9	17.8	13.9	124.4
647404	28.2	39.6	36.2	21.7	15.1	140.8
647405	38.1	42.8	32.0	25.3	24.6	162.8

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ FEMALE RATS

GROUP: VIII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647436	38.8	44.9	34.1	27.3	-6.2	138.9
647437	48.8	35.8	32.8	33.4	4.0	154.8
647438	40.2	49.5	48.5	44.3	27.9	210.4
647439	34.6	42.8	30.1	27.3	23.2	158.0
647440	30.9	47.3	42.0	22.9	29.0	172.1
647441	31.4	46.7	38.8	27.5	19.4	163.8
647442	32.2	40.5	35.1	10.9	23.4	142.1
647443	31.2	44.1	32.8	26.3	26.7	161.1
647444	32.7	42.4	29.7	16.4	33.5	154.7
647445	25.5	46.3	42.9	28.4	30.4	173.5
647446	33.4	50.8	38.6	27.1	11.7	161.6
647447	43.0	46.9	37.5	20.2	-0.3	147.3

APPENDIX KK

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL FOOD CONSUMPTION: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL FOOD CONSUMPTION: F₁ GENERATION

EXPLANATORY NOTES

Notes

Day of weaning =

Test Day 1.

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ MALE RATS

GROUP: I-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647068	12.3	20.5	20.4	22.9	25.6	20.3
647069	15.2	22.8	27.3	30.3	9.2	21.0
647070	12.7	20.1	25.1	26.7	26.1	22.2
647071	15.3	23.6	27.1	31.1	24.4	24.3
647072	12.6	20.0	23.6	26.1	10.2	18.5
647073	14.4	18.8	23.3	24.8	9.5	18.2
647074	12.0	20.6	25.1	30.3	21.8	22.0
647075	12.7	18.7	22.7	23.9	12.8	18.2
647076	11.0	18.2	22.9	27.8	23.3	20.6
647077	13.5	19.6	25.5	25.0	30.9	22.9
647078	12.0	20.3	23.7	25.6	31.0	22.5
647079	11.1	18.6	24.1	29.5	26.2	21.9
647080	12.0	18.0	23.8	27.0	25.8	21.4

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ MALE RATS

GROUP: III-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647123	11.5	19.4	23.5	26.7	46.6	25.5
647124	11.9	19.6	23.1	24.3	26.5	21.1
647125	11.7	18.0	21.8	25.0	24.0	20.1
647126	11.0	17.2	21.4	25.7	2.3	15.5
647127	11.5	18.1	22.7	25.6	7.8	17.1
647128	13.2	19.2	24.6	21.6	28.6	21.4
647129	12.2	19.3	24.9	24.1	22.8	20.7
647130	13.3	20.1	24.5	28.1	31.1	23.4
647131	14.1	20.4	25.0	28.8	28.5	23.4
647132	12.2	18.9	22.0	22.7	25.9	20.3
647133	11.8	18.8	21.9	23.8	22.9	19.8
647134	14.1	21.2	24.6	31.2	14.4	21.1
647135	11.9	19.6	25.0	25.4	25.2	21.4
647136	9.8	15.1	19.8	22.5	25.2	18.5
647137	10.9	15.3	20.6	22.8	25.4	19.0
647138	14.0	19.0	22.2	24.7	15.5	19.1

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ MALE RATS

GROUP: V-1

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647184	10.7	16.9	21.7	25.0	21.1	19.1
647185	11.6	18.6	24.4	29.4	25.7	21.9
647186	9.6	17.4	24.9	26.0	23.5	20.3
647187	13.7	20.9	26.0	29.3	17.7	21.5
647188	12.0	20.6	24.2	30.2	15.4	20.5
647189	12.4	20.9	25.9	26.1	27.2	22.5
647190	11.5	19.1	25.2	28.2	25.2	21.8
647191	12.9	20.6	24.7	26.2	25.4	22.0
647192	11.1	18.4	24.4	29.5	24.6	21.6
647193	11.3	17.1	21.8	26.3	24.9	20.3
647194	11.6	18.7	23.3	27.2	26.2	21.4
647195	15.6	21.2	22.8	24.5	25.5	21.9

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ MALE RATS

GROUP: VII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647230	12.0	18.0	23.4	26.0	28.0	21.5
647231	12.8	15.0	22.4	28.1	4.2	16.5
647232	12.5	19.4	24.7	34.5	8.1	19.8
647233	10.9	16.9	20.8	24.1	23.0	19.1
647234	12.9	19.5	25.3	28.7	24.2	22.2
647235	10.3	16.8	21.6	24.3	23.9	19.4
647236	11.0	17.9	23.3	26.0	28.3	21.3
647237	10.3	17.3	24.5	24.7	23.5	20.1
647238	11.2	17.2	21.4	24.8	25.7	20.1
647239	11.2	15.7	23.2	27.4	24.7	20.4
647240	10.1	16.2	20.1	23.6	26.5	19.3
647241	12.8	18.5	22.4	22.7	28.0	20.9

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ FEMALE RATS

GROUP: II-1

DOSE: 0 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647277	12.1	16.1	18.6	18.5	19.5	17.0
647278	12.5	17.1	16.6	17.1	17.7	16.2
647279	11.2	15.8	15.4	14.9	15.4	14.6
647280	11.0	15.6	17.5	17.9	17.8	16.0
647281	11.9	16.9	18.6	18.7	18.5	16.9
647282	11.4	16.3	17.7	18.8	18.5	16.5
647283	10.8	16.6	20.1	20.1	18.5	17.2
647284	12.4	15.3	17.9	16.7	17.4	15.9
647285	9.6	15.4	17.7	17.2	17.3	15.5
647286	11.0	15.5	18.3	20.6	17.8	16.6
647287	13.2	20.9	18.9	20.9	20.4	18.9
647288	11.4	17.0	17.7	18.3	18.3	16.6
647289	11.0	15.2	16.3	16.0	15.5	14.8

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ FEMALE RATS

GROUP: IV-1

DOSE: 25 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647326	9.9	16.8	17.3	17.3	46.8	21.6
647327	12.8	16.9	19.9	18.1	19.4	17.4
647328	12.2	16.4	17.4	17.4	17.2	16.1
647329	11.6	16.2	18.4	19.7	20.4	17.3
647330	10.9	15.4	18.3	18.2	18.8	16.3
647331	13.3	19.3	23.4	23.0	25.9	21.0
647332	11.6	18.4	22.4	21.5	23.7	19.5
647333	12.3	16.1	17.4	16.9	14.7	15.5
647334	12.3	20.2	23.3	22.3	27.0	21.0
647335	13.1	18.2	17.2	16.2	18.0	16.5
647336	9.0	13.7	14.9	14.4	15.5	13.5
647337	11.8	17.1	19.9	20.2	22.5	18.3
647338	10.5	16.3	17.3	18.1	17.3	15.9
647339	10.7	14.9	16.6	15.8	15.4	14.7
647340	10.2	15.4	16.3	16.8	17.2	15.2
647341	10.8	15.1	15.8	16.8	16.6	15.0
647342	11.9	16.7	17.0	17.6	18.1	16.2

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ FEMALE RATS

GROUP: VI-1.

DOSE: 100 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647394	11.4	15.7	16.5	16.8	17.7	15.6
647395	11.7	16.3	17.7	19.0	19.4	16.8
647396	11.1	16.6	19.8	19.5	19.9	17.4
647397	10.7	14.3	17.0	16.1	16.0	14.8
647398	12.8	16.0	18.5	20.1	19.8	17.5
647399	7.9	18.3	19.9	21.3	21.5	17.8
647400	10.5	16.4	19.5	20.3	19.7	17.3
647401	13.5	17.7	19.7	19.6	20.2	18.1
647402	13.1	16.2	19.6	19.7	19.9	17.7
647403	9.4	15.6	15.5	15.8	15.6	14.4
647404	9.4	15.1	16.9	17.5	17.1	15.2
647405	11.7	18.4	20.9	21.5	20.9	18.7

INDIVIDUAL FOOD CONSUMPTION (grams/day) BY F₁ FEMALE RATS

GROUP: VIII-1

DOSE: 250 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
647436	12.0	17.7	18.5	19.8	16.5	16.9
647437	12.8	15.7	17.6	19.8	14.2	16.0
647438	10.2	14.8	18.6	19.5	19.4	16.5
647439	9.7	14.6	16.6	17.5	18.4	15.4
647440	10.2	15.1	18.6	19.4	19.8	16.6
647441	9.6	14.5	17.5	17.6	17.9	15.4
647442	10.6	14.9	17.2	17.1	17.0	15.4
647443	9.6	16.0	17.2	18.0	18.9	15.9
647444	11.3	16.8	16.4	16.7	18.3	15.9
647445	8.5	14.5	12.0	18.9	19.6	14.7
647446	9.0	16.5	19.6	19.0	20.2	16.9
647447	12.2	18.5	19.6	20.5	17.5	17.7

APPENDIX LL

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL CLINICAL OBSERVATIONS: F₁ GENERATION

EXPLANATORY NOTES

Notes

Day of weaning = Test Day 1.

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

GROUP: I-1 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647068	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647069	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647070	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	18	18
647071	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647072	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647073	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647074	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647075	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647076	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647077	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647078	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647079	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
647080	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

GROUP: III-1

DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647123	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
647124	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647125	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647126	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647127	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647128	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
647129	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647130	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
647131	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
647132	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647133	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
647134	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647135	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647136	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
647137	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
647138	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

GROUP: V-1

DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647184	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647185	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
647186	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	29	29
647187	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647188	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
647189	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
647190	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
647191	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647192	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
647193	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
647194	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647195	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

GROUP: VII-1 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647230	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
647231	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647232	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647233	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
647234	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
647235	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647236	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21
647237	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
647238	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
647239	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
647240	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
647241	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	21	21

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

GROUP: II-1 DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647277	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8
647278	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
647279	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	9	9
647280	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
647281	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647282	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647283	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647284	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647285	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647286	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	18	18
647287	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647288	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647289	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

GROUP: IV-1 DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647326	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647327	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647328	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	19	19
647329	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647330	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	15	15
647331	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647332	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647333	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647334	VAGINAL PATENCY COMPLETE ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 40	13 40	13 40
647335	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647336	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647337	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8
647338	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647339	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647340	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647341	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647342	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

GROUP: VI-1 DOSE: 100 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647394	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647395	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	17	17
647396	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647397	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
647398	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647399	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
647400	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647401	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647402	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647403	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647404	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647405	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

GROUP: VIII-1 DOSE: 250 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
647436	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
647437	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647438	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	20	20
647439	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
647440	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
647441	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647442	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647443	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647444	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647445	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
647446	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
647447	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11