

AR226-3222

404

TRADE SECRET*Study Title*

H-24768: Subchronic Toxicity
90-Day Gavage Study in Rats
with One-Generation Reproduction Evaluations

Volume 4 of 5

Laboratory Project ID: DuPont-5990

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

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STUDY COMPLETED ON: January 18, 2002

PERFORMING LABORATORY: E.I. du Pont de Nemours and Company
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INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646507 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

LIVER :
HYPERPLASIA, BILIARY, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
KIDNEYS, SPLEEN, THYROID GLAND

646511 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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,

646511 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

646511 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 :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

646530 Terminal Sacrifice
Killed on Day : 183
Exposure Group : 3-Month Recovery
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646537 Terminal Sacrifice
 Killed on Day : 96
 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 :

THYROID GLAND :
 ALTERATION, COLLOID, minimal.
UTERUS :
 DILATATION, LUMEN, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

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,

646537 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

646537 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, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, BONE
MARROW, NOSE I & II, NOSE III & IV

646538 Terminal Sacrifice
Killed on Day : 96
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 :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646538 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

646538 Continued from previous page

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 I & II, NOSE
III & IV

646549 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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

646549 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

646549 Continued from previous page

Histopathology :

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :

LIVER, SPLEEN, THYROID GLAND

646551

Terminal Sacrifice

Killed on Day : 124

Exposure Group : 1-Month Recovery

Animal is signed off from necropsy

Gross Pathology :

KIDNEYS :

CYST, CLEAR, LEFT, 3MM 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, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE

646551 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

646551 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

646560 Terminal Sacrifice
Killed on Day : 96
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 :

PARATHYROID GLANDS :
MISSING.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646560 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

646560 Continued from previous page

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, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX, EYE(S)
WITH OPTIC NERVE, SKIN, MAMMARY GLAND (FEMALE), OVARIES,
UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT, STERNUM, BONE
MARROW, NOSE I & II, NOSE III & IV

ORGANS NOT EXAMINED:

PARATHYROID GLANDS

646565

Terminal Sacrifice

Killed on Day : 124

Exposure Group : 1-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

646565 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

646565 Continued from previous page

Histopathology :

LIVER :

INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, minimal.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :

KIDNEYS, SPLEEN, THYROID GLAND

646580

Terminal Sacrifice

Killed on Day : 124

Exposure Group : 1-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 :

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

646580 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

646580 Continued from previous page

Histopathology :

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

646581 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

KIDNEYS :
DILATATION, RIGHT, PELVIS.
CYST, RIGHT, 2MM DIAMETER.

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, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, NOSE

Histopathology :

KIDNEYS :
HYDRONEPHROSIS, UNILATERAL, moderate.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646581 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

646581 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
LIVER, SPLEEN, THYROID GLAND

646586 Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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 :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646588 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS ,

Histopathology :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN, THYROID GLAND

646592 Terminal Sacrifice
 Killed on Day : 96
 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,

646592 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

646592 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 :

LIVER :
FATTY CHANGE, MEDIAN CLEFT, mild.
PANCREAS :
INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, minimal.
PARATHYROID GLANDS :
MISSING.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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, 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 I & II, NOSE
III & IV

ORGANS NOT EXAMINED:
PARATHYROID GLANDS

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646597 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

 No Macroscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

 LIVER :
 FATTY CHANGE, MEDIAN CLEFT, minimal.
 KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
 PYELONEPHRITIS, UNILATERAL, minimal.
 THYROID GLAND :
 ALTERATION, COLLOID, minimal.
 CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

 No Microscopic Abnormality Observed :
 SPLEEN

646612 Terminal Sacrifice
 Killed on Day : 96
 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,

646612 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

646612 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 :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic 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, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE I & II, NOSE III & IV

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646613 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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 :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646617 Terminal Sacrifice
Killed on Day : 96
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, FOCAL, minimal.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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, PARATHYROID GLANDS,

646617 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

646617 Continued from previous page

Histopathology :

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

646627 Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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.

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646627 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

646627 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646649 Terminal Sacrifice
Killed on Day : 96
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, FOCAL, minimal.
SPLEEN :
PIGMENT INCREASED, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646649 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

646649 Continued from previous page

Histopathology :

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, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE I & II, NOSE III & IV

646652

Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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

646652 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

646652 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

646659 Terminal Sacrifice
Killed on Day : 96
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 :
FATTY CHANGE, MEDIAN CLEFT, minimal.

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646659 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

646659 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 I & II, NOSE III & IV

646665 Terminal Sacrifice
 Killed on Day : 96
 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

646665 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

646665 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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 I & II, NOSE
III & IV

646676 Terminal Sacrifice
Killed on Day : 96
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,

646676 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

646676 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 :

LIVER :
INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE I & II, NOSE III & IV

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646502 Terminal Sacrifice
 Killed on Day : 96
 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 :

KIDNEYS :
 INFLAMMATION, LYMPHOID, CORTICAL, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN, THYROID GLAND

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646522 Terminal Sacrifice
 Killed on Day : 96
 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 :

THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646531 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

646531 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

646531 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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

646567 Terminal Sacrifice
Killed on Day : 96
Exposure Group : 90-Day Exposure
Animal is signed off from necropsy

Gross Pathology :

PITUITARY GLAND :
LARGE, mild.

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

Histopathology :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

646567 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

646567 Continued from previous page

Histopathology :

PITUITARY GLAND :
 NO MICROSCOPIC EVIDENCE OF MACROSCOPIC FINDING.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, SPLEEN, PITUITARY GLAND, THYROID GLAND

646568 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646576 Terminal Sacrifice
 Killed on Day : 96
 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 :

THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref	Microscopic & Macroscopic Findings
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646595	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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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 :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN, THYROID GLAND

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646621 Terminal Sacrifice
 Killed on Day : 96
 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 :

SPLEEN :
HEMATOPOIESIS, INCREASED, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, THYROID GLAND

646625 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

646625 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

646625 Continued from previous page

Histopathology :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, SPLEEN

646626 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

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

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646635 Terminal Sacrifice
 Killed on Day : 96
 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 :

THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref	Microscopic & Macroscopic Findings
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646636	Terminal Sacrifice Killed on Day : 183 Exposure Group : 3-Month Recovery Animal is signed off from necropsy
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Gross Pathology :

THYROID GLAND :
ONLY ONE THYROID PRESENT AT TRIMMING, NO THYROID WEIGHTS
WERE TAKEN.

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

THYROID GLAND :
ALTERATION, COLLOID, minimal.

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646660	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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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,

646660 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

646660 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.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646664 Terminal Sacrifice
 Killed on Day : 96
 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,

646664 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

646664 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.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646673 Terminal Sacrifice
Killed on Day : 96
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,

646673 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

646673 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.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref	Microscopic & Macroscopic Findings
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646501	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646505 Terminal Sacrifice
 Killed on Day : 96
 Exposure Group : 90-Day Exposure
 Animal is signed off from necropsy

Gross Pathology :

PITUITARY GLAND :

LARGE.

UTERUS :

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

Histopathology :

LIVER :

HYPERTROPHY, CENTRIOBULAR, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, mild.

SPLEEN :

HEMATOPOIESIS, INCREASED, minimal.

THYROID GLAND :

ALTERATION, COLLOID, minimal.

UTERUS :

DILATATION, LUMEN, mild.

646505 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

646505 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646510 Terminal Sacrifice
 Killed on Day : 96
 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 :
 HYPERTROPHY, CENTRIOLOBULAR, minimal.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.

646510 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

646510 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646533 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

xx : ANIMAL CAME TO NECROPSY AK, ONLY FLOURINE AND HISTO SAVED..

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

SPLEEN :
PIGMENT INCREASED.
THYROID GLAND :
MISSING.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS

ORGANS NOT EXAMINED:
THYROID GLAND

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref	Microscopic & Macroscopic Findings
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646534	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646556 Terminal Sacrifice
 Killed on Day : 96
 Exposure Group : 90-Day Exposure
 Animal is signed off from necropsy

Gross Pathology :

PITUITARY GLAND :

LARGE.

MAMMARY GLAND (FEMALE) :

LARGE, VENTRAL.

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, OVARIES, UTERUS, URINARY
BLADDER, FEMUR/KNEE JOINT, STERNUM, NOSE

Histopathology :

LIVER :

HYPERTROPHY, CENTRIOLOBULAR, minimal.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

SPLEEN :

HEMATOPOIESIS, INCREASED, minimal.

THYROID GLAND :

ALTERATION, COLLOID, mild.

HYPERTROPHY, FOLLICULAR, minimal.

MAMMARY GLAND (FEMALE) :

HYPERPLASIA, LOBULAR, mild.

646556 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

646556 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646578 Terminal Sacrifice
 Killed on Day : 96
 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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

646578 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

646578 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
KIDNEYS, SPLEEN

646608 Terminal Sacrifice
Killed on Day : 96
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 :

THYROID GLAND :
ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646624 Terminal Sacrifice
 Killed on Day : 96
 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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646629 Terminal Sacrifice
 Killed on Day : 96
 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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, mild.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

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

Animal Ref Microscopic & Macroscopic Findings

646630 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, moderate.
SPLEEN :
PIGMENT INCREASED, minimal.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER

646632 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

646632 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

646632 Continued from previous page

Histopathology :

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, mild.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :

LIVER, SPLEEN

646633

Terminal Sacrifice

Killed on Day : 96

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

646633 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

646633 Continued from previous page

Histopathology :

LIVER :
 HYPERTROPHY, CENTRIOBULAR, minimal.
SPLEEN :
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, moderate.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 KIDNEYS

646634 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

KIDNEYS :
 SMALL, RIGHT, IRREGULAR.

No Macroscopic Abnormality Observed :
 LIVER, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.

646634 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

646634 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

646656 Terminal Sacrifice
Killed on Day : 183
Exposure Group : 3-Month Recovery
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, mild.
THYROID GLAND :
ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646506 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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 :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646508 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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 :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, mild.
THYROID GLAND :
 ALTERATION, COLLOID, moderate.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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646509	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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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 :
 HYPERTROPHY, CENTRIOBULAR, mild.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
 PIGMENT INCREASED, minimal.
THYROID GLAND :
 HYPERTROPHY, FOLLICULAR, mild.
 ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

646509 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646509 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

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, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
III & IV

646523 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

LIVER :
 INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, mild.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, mild.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

646523 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646523 Continued from previous page

Histopathology :

 No Microscopic Abnormality Observed :
 SPLEEN

646528 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

 No Macroscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

 KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
 THYROID GLAND :
 ALTERATION, COLLOID, mild.
 CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

 No Microscopic Abnormality Observed :
 LIVER, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646535 Terminal Sacrifice
 Killed on Day : 96
 Exposure Group : 90-Day Exposure
 Animal is signed off from necropsy

Gross Pathology :

MANDIBULAR LYMPH NODE :
DISCOLORATION, BILATERAL.

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, 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 :
HYPERTROPHY, CENTRIOBULAR, mild.
SPLEEN :
PIGMENT INCREASED, minimal.
MANDIBULAR LYMPH NODE :
CONGESTION, mild.
THYROID GLAND :
ALTERATION, COLLOID, mild.
HYPERTROPHY, FOLLICULAR, minimal.
PARATHYROID GLANDS :
MISSING.

646535 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646535 Continued from previous page

Histopathology :

EYE(S) WITH OPTIC NERVE :
HEMORRHAGE/INFLAMMATION (BLEEDING PROCEDURE).
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

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, THYMUS, ADRENAL GLANDS, SCIATIC NERVE, PITUITARY
GLAND, TRACHEA, ESOPHAGUS, PHARYNX/LARYNX, SKIN,
MAMMARY GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
III & IV

ORGANS NOT EXAMINED:
PARATHYROID GLANDS

646536 Terminal Sacrifice
Killed on Day : 96
Exposure Group : 90-Day Exposure
Animal is signed off from necropsy

Gross Pathology :

LIVER :
LARGE.

646536 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646536 Continued from previous page

Gross Pathology :

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,
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 :

HYPERTROPHY, CENTRIOLOBULAR, moderate.

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, moderate.

SPLEEN :

PIGMENT INCREASED, minimal.

HEMATOPOIESIS, INCREASED, mild.

THYROID GLAND :

ALTERATION, COLLOID, moderate.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :

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,

646536 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646536 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :
PHARYNX/LARYNX, EYE(S) WITH OPTIC NERVE, SKIN, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
III & IV

646540 Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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 :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, moderate.
HYPERTROPHY, FOLLICULAR, mild.

646540 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646540 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

646542 Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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 :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, moderate.
THYROID GLAND :
ALTERATION, COLLOID, moderate.
HYPERTROPHY, FOLLICULAR, minimal.

646542 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646542 Continued from previous page

Histopathology :

CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, SPLEEN

646545 Terminal Sacrifice
Killed on Day : 124
Exposure Group : 1-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 :

KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
HEMATOPOIESIS, INCREASED, minimal.

646545 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646545 Continued from previous page

Histopathology :

 THYROID GLAND :
 ALTERATION, COLLOID, mild.

 CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

 No Microscopic Abnormality Observed :
 LIVER

646548 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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 :

 KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

646548 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646548 Continued from previous page

Histopathology :

THYROID GLAND :
 ALTERATION, COLLOID, moderate.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, SPLEEN

646577 Terminal Sacrifice
 Killed on Day : 96
 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 :
 HYPERTROPHY, CENTRIOBULAR, mild.

646577 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646577 Continued from previous page

Histopathology :

SPLEEN :

PIGMENT INCREASED, minimal.
HEMATOPOIESIS, INCREASED, minimal.

THYROID GLAND :

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

UTERUS :

DILATATION, LUMEN, minimal.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

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, NOSE I & II, NOSE III & IV

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646593 Terminal Sacrifice
Killed on Day : 96
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 :
 HYPERTROPHY, CENTRIOBULAR, mild.
SPLEEN :
 PIGMENT INCREASED, minimal.
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

646593 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646593 Continued from previous page

Histopathology :

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, UTERUS, URINARY BLADDER, FEMUR/KNEE JOINT,
STERNUM, BONE MARROW, NOSE I & II, NOSE III & IV

646599 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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

646599 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646599 Continued from previous page

Histopathology :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
 LIVER, SPLEEN

646601 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

xx :
 ANIMALS CAME TO NECROPSY AK, ONLY FLOURINE AND HISTO TISSUE
 SAVED..

No Macroscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, mild.
SPLEEN :
 PIGMENT INCREASED, minimal.

646601 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646601 Continued from previous page

Histopathology :

THYROID GLAND :
MISSING.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER

ORGANS NOT EXAMINED:
THYROID GLAND

646609 Terminal Sacrifice
Killed on Day : 96
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

646609 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646609 Continued from previous page

Histopathology :

LIVER :

 HYPERTROPHY, CENTRIOBULAR, mild.

SPLEEN :

 PIGMENT INCREASED, minimal.

 HEMATOPOIESIS, INCREASED, minimal.

THYROID GLAND :

 ALTERATION, COLLOID, mild.

 HYPERTROPHY, FOLLICULAR, minimal.

UTERUS :

 DILATATION, LUMEN, minimal.

CAUSE OF DEATH :

 SACRIFICE BY DESIGN.

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, NOSE I & II, NOSE III & IV

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646610 Terminal Sacrifice
Killed on Day : 96
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 :
 HYPERTROPHY, CENTRIOBULAR, minimal.
 NECROSIS, INDIVIDUAL CELL, mild.
 INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, minimal.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
SPLEEN :
 PIGMENT INCREASED, minimal.
 HEMATOPOIESIS, INCREASED, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, minimal.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

646610 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646610 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

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, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
III & IV

646614

Terminal Sacrifice
Killed on Day : 96
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

646614 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646614 Continued from previous page

Histopathology :

LIVER :

 HYPERTROPHY, CENTRIOBULAR, mild.

KIDNEYS :

 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.

SPLEEN :

 PIGMENT INCREASED, minimal.

 HEMATOPOIESIS, INCREASED, minimal.

THYROID GLAND :

 ALTERATION, COLLOID, severe.

 HYPERTROPHY, FOLLICULAR, mild.

CAUSE OF DEATH :

 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :

 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, UTERUS, URINARY BLADDER,
 FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
 III & IV

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646618 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-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 :

LIVER :
 HYPERTROPHY, CENTRIOBULAR, minimal.
KIDNEYS :
 NEPHROPATHY, CHRONIC PROGRESSIVE, minimal.
THYROID GLAND :
 ALTERATION, COLLOID, moderate.
 HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646620 Terminal Sacrifice
 Killed on Day : 183
 Exposure Group : 3-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

 No Microscopic Abnormality Observed :
 LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

 LIVER :
 FATTY CHANGE, MEDIAN CLEFT, minimal.
 CAUSE OF DEATH :
 SACRIFICE BY DESIGN.

 No Microscopic Abnormality Observed :
 KIDNEYS, SPLEEN, THYROID GLAND

646637 Terminal Sacrifice
 Killed on Day : 124
 Exposure Group : 1-Month Recovery
 Animal is signed off from necropsy

Gross Pathology :

 STOMACH :
 ULCER/EROSION, GLANDULAR, 3MM DIA.

646637 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646637 Continued from previous page

Gross Pathology :

No Macroscopic Abnormality Observed :
LIVER, KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, SPLEEN,
AORTA, BRAIN, SPINAL CORD, 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 :

STOMACH :
EROSION/ULCER, ACUTE, minimal.
THYROID GLAND :
ALTERATION, COLLOID, mild.
HYPERTROPHY, FOLLICULAR, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref	Microscopic & Macroscopic Findings
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646650	Terminal Sacrifice Killed on Day : 124 Exposure Group : 1-Month Recovery Animal is signed off from necropsy
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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.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed :
LIVER, KIDNEYS, SPLEEN

646657	Terminal Sacrifice Killed on Day : 96 Exposure Group : 90-Day Exposure Animal is signed off from necropsy
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Gross Pathology :

LIVER :
LARGE.

646657 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646657 Continued from previous page

Gross Pathology :

PITUITARY GLAND :
LARGE, mild.

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, 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 :
HYPERTROPHY, CENTRIOLOBULAR, mild.
KIDNEYS :
NEPHROPATHY, CHRONIC PROGRESSIVE, mild.
SPLEEN :
PIGMENT INCREASED, minimal.
HEMATOPOIESIS, INCREASED, mild.
THYROID GLAND :
ALTERATION, COLLOID, mild.
HYPERTROPHY, FOLLICULAR, mild.
UTERUS :
DILATATION, LUMEN, minimal.
CAUSE OF DEATH :
SACRIFICE BY DESIGN.

646657 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646657 Continued from previous page

Histopathology :

No Microscopic Abnormality Observed :

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, NOSE I & II, NOSE III & IV

646667

Terminal Sacrifice
Killed on Day : 183
Exposure Group : 3-Month Recovery
Animal is signed off from necropsy

Gross Pathology :

No Macroscopic Abnormality Observed :

LIVER, KIDNEYS, SPLEEN, THYROID GLAND, PARATHYROID GLANDS

Histopathology :

KIDNEYS :

NEPHROPATHY, CHRONIC PROGRESSIVE, mild.

SPLEEN :

PIGMENT INCREASED, minimal.

THYROID GLAND :

ALTERATION, COLLOID, moderate.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

646667 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646667 Continued from previous page

Histopathology :

 No Microscopic Abnormality Observed :
 LIVER

646669 Terminal Sacrifice
 Killed on Day : 96
 Exposure Group : 90-Day Exposure
 Animal is signed off from necropsy

Gross Pathology :

 SKIN :
 ALOPECIA, BILATERAL, HINDLIMB.

 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, MAMMARY GLAND
 (FEMALE), OVARIES, UTERUS, URINARY BLADDER, FEMUR/KNEE
 JOINT, STERNUM, NOSE

Histopathology :

 LIVER :
 HYPERTROPHY, CENTRIOLOBULAR, mild.
 NECROSIS, INDIVIDUAL CELL, minimal.
 INFLAMMATION, SUBACUTE/CHRONIC, FOCAL, minimal.

646669 Continued on the next page

INDIVIDUAL ANIMAL GROSS AND MICROSCOPIC OBSERVATIONS

Dose Group : VIII - 500 mg/kg/day Sex: Females

Animal Ref Microscopic & Macroscopic Findings

646669 Continued from previous page

Histopathology :

SPLEEN :

PIGMENT INCREASED, minimal.

STOMACH :

EROSION/ULCER, ACUTE, minimal.

THYROID GLAND :

ALTERATION, COLLOID, moderate.

HYPERTROPHY, FOLLICULAR, minimal.

SKIN :

ALOPECIA/HYPOTRICHOSIS, mild.

CAUSE OF DEATH :

SACRIFICE BY DESIGN.

No Microscopic Abnormality Observed:

KIDNEYS, LUNGS, HEART, SKELETAL MUSCLE, AORTA, BRAIN,
SPINAL CORD, 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, MAMMARY
GLAND (FEMALE), OVARIES, UTERUS, URINARY BLADDER,
FEMUR/KNEE JOINT, STERNUM, BONE MARROW, NOSE I & II, NOSE
III & IV

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 72-86 = Cohabitation period

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: I-0

DOSE: 0 MG/KG/DAY

TEST DAYS:	77	84	91	98
ANIMAL NUMBER				
646490	484.9	502.9	515.2	528.8
646440	492.9	505.3	527.9	535.6
646424	507.4	524.3	485.8	514.2
646402	569.2	573.3	581.4	595.7
646392	590.9	591.7	609.0	622.1
646473	603.6	634.2	657.7	689.1
646395	576.2	590.7	605.3	614.3
646352	490.6	499.2	510.4	524.4
646357	562.5	565.6	572.4	584.0
646409	575.7	593.3	607.7	612.9
646328	599.2	618.4	639.0	646.0
646479	727.7	754.6	773.3	782.8
646470	550.6	578.0	582.0	593.5
646461	540.1	559.8	572.2	590.2
646480	468.6	482.9	495.7	503.6
646383	606.2	612.6	633.1	651.7
646445	488.4	502.4	515.2	530.7
646358	529.9	554.9	564.3	573.0
646425	529.1	548.6	559.4	567.6
646408	565.0	581.3	594.4	614.8

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: III-0

DOSE: 25 MG/KG/DAY

TEST DAYS:	77	84	91	98
ANIMAL NUMBER				
646378	509.2	508.8	523.8	527.2
646483	584.5	594.9	608.7	626.7
646363	540.3	560.9	583.8	601.6
646334	570.5	583.7	597.0	610.6
646493	606.9	628.3	644.3	661.1
646404	589.9	604.5	618.7	636.8
646415	570.8	581.8	593.4	616.1
646410	541.4	548.3	563.9	575.9
646340	487.5	497.8	519.5	527.5
646354	547.9	559.5	574.2	591.3
646467	603.6	576.0	626.3	648.1
646381	559.2	576.8	583.5	606.2
646342	609.3	616.8	631.9	659.3
646450	549.4	558.1	575.4	585.3
646326	560.1	566.1	570.9	588.3
646377	558.4	575.4	585.6	605.1
646478	708.5	745.7	776.1	799.4
646350	555.8	569.5	579.5	610.0
646333	515.8	517.4	535.1	558.9
646486	443.6	448.0	454.3	475.6

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: V-0

DOSE: 100 MG/KG/DAY

TEST DAYS:	77	84	91	98
ANIMAL NUMBER				
646353	489.3	516.4	537.1	556.7
646341	545.0	565.5	575.0	591.8
646356	537.3	546.6	566.2	587.2
646330	529.1	524.8	528.3	539.5
646499	557.5	573.2	586.7	598.6
646400	540.0	540.8	547.1	564.4
646417	511.8	527.2	539.7	551.2
646338	499.5	522.5	536.1	542.9
646394	574.4	587.5	609.5	624.9
646387	507.1	519.7	523.3	541.3
646447	500.2	509.7	520.6	538.8
646336	487.4	485.3	490.8	499.1
646366	515.3	533.1	543.5	555.8
646496	507.1	529.1	543.7	549.4
646375	549.3	562.4	569.6	572.2
646465	518.9	530.6	545.3	549.9
646390	456.8	481.9	498.7	528.3
646429	560.3	571.5	586.0	597.9
646476	465.5	485.0	512.5	529.6
646348	498.6	503.5	510.8	526.6

INDIVIDUAL BODY WEIGHTS (grams) OF P₁ MALE RATS

GROUP: VII-0

DOSE: 500 MG/KG/DAY

TEST DAYS:	77	84	91	98
ANIMAL NUMBER				
646382	407.7	417.8	432.1	444.7
646406	453.5	460.4	470.3	479.3
646491	501.7	513.4	527.1	544.2
646351	465.1	482.0	493.3	500.8
646405	453.0	457.5	469.0	480.7
646418	468.4	470.8	480.8	496.2
646362	410.8	408.2	411.7	423.4
646497	436.9	452.8	468.6	467.9
646401	518.1	526.3	528.9	536.5
646498	543.4	559.7	569.3	604.7
646386	562.5	582.4	592.3	617.0
646332	389.6	387.4	407.0	410.8
646441	474.3	475.5	490.0	511.4
646452	426.3	432.9	445.0	443.7
646365	435.5	456.6	465.3	473.0
646393	477.2	489.3	503.5	434.4
646359	503.4	514.1	506.8	512.6
646451	393.3	415.8	426.8	439.5

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 72-86 = Cohabitation period

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: I-0

DOSE: 0 MG/KG/DAY

TEST DAYS:	77-84	84-91	91-98	77-98
ANIMAL NUMBER				
646490	18.0	12.3	13.6	43.9
646440	12.4	22.6	7.7	42.7
646424	16.9	-38.5	28.4	6.8
646402	4.1	8.1	14.3	26.5
646392	0.8	17.3	13.1	31.2
646473	30.6	23.5	31.4	85.5
646395	14.5	14.6	9.0	38.1
646352	8.6	11.2	14.0	33.8
646357	3.1	6.8	11.6	21.5
646409	17.6	14.4	5.2	37.2
646328	19.2	20.6	7.0	46.8
646479	26.9	18.7	9.5	55.1
646470	27.4	4.0	11.5	42.9
646461	19.7	12.4	18.0	50.1
646480	14.3	12.8	7.9	35.0
646383	6.4	20.5	18.6	45.5
646445	14.0	12.8	15.5	42.3
646358	25.0	9.4	8.7	43.1
646425	19.5	10.8	8.2	38.5
646408	16.3	13.1	20.4	49.8

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: III-0

DOSE: 25 MG/KG/DAY

TEST DAYS:	77-84	84-91	91-98	77-98
ANIMAL NUMBER				
646378	-0.4	15.0	3.4	18.0
646483	10.4	13.8	18.0	42.2
646363	20.6	22.9	17.8	61.3
646334	13.2	13.3	13.6	40.1
646493	21.4	16.0	16.8	54.2
646404	14.6	14.2	18.1	46.9
646415	11.0	11.6	22.7	45.3
646410	6.9	15.6	12.0	34.5
646340	10.3	21.7	8.0	40.0
646354	11.6	14.7	17.1	43.4
646467	-27.6	50.3	21.8	44.5
646381	17.6	6.7	22.7	47.0
646342	7.5	15.1	27.4	50.0
646450	8.7	17.3	9.9	35.9
646326	6.0	4.8	17.4	28.2
646377	17.0	10.2	19.5	46.7
646478	37.2	30.4	23.3	90.9
646350	13.7	10.0	30.5	54.2
646333	1.6	17.7	23.8	43.1
646486	4.4	6.3	21.3	32.0

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: V-0

DOSE: 100 MG/KG/DAY

TEST DAYS:	77-84	84-91	91-98	77-98
ANIMAL NUMBER				
646353	27.1	20.7	19.6	67.4
646341	20.5	9.5	16.8	46.8
646356	9.3	19.6	21.0	49.9
646330	-4.3	3.5	11.2	10.4
646499	15.7	13.5	11.9	41.1
646400	0.8	6.3	17.3	24.4
646417	15.4	12.5	11.5	39.4
646338	23.0	13.6	6.8	43.4
646394	13.1	22.0	15.4	50.5
646387	12.6	3.6	18.0	34.2
646447	9.5	10.9	18.2	38.6
646336	-2.1	5.5	8.3	11.7
646366	17.8	10.4	12.3	40.5
646496	22.0	14.6	5.7	42.3
646375	13.1	7.2	2.6	22.9
646465	11.7	14.7	4.6	31.0
646390	25.1	16.8	29.6	71.5
646429	11.2	14.5	11.9	37.6
646476	19.5	27.5	17.1	64.1
646348	4.9	7.3	15.8	28.0

INDIVIDUAL BODY WEIGHT GAINS (grams) OF P₁ MALE RATS

GROUP: VII-0

DOSE: 500 MG/KG/DAY

TEST DAYS:	77-84	84-91	91-98	77-98
ANIMAL NUMBER				
646382	10.1	14.3	12.6	37.0
646406	6.9	9.9	9.0	25.8
646491	11.7	13.7	17.1	42.5
646351	16.9	11.3	7.5	35.7
646405	4.5	11.5	11.7	27.7
646418	2.4	10.0	15.4	27.8
646362	-2.6	3.5	11.7	12.6
646497	15.9	15.8	-0.7	31.0
646401	8.2	2.6	7.6	18.4
646498	16.3	9.6	35.4	61.3
646386	19.9	9.9	24.7	54.5
646332	-2.2	19.6	3.8	21.2
646441	1.2	14.5	21.4	37.1
646452	6.6	12.1	-1.3	17.4
646365	21.1	8.7	7.7	37.5
646393	12.1	14.2	-69.1	-42.8
646359	10.7	-7.3	5.8	9.2
646451	22.5	11.0	12.7	46.2

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 was delivered; data were excluded from statistical analysis.
- b* No gestation data were collected since no copulation plug was observed; however a litter was delivered.
- c* No gestation data were collected since no copulation plug was observed; no litter was delivered.
- d* Start of gestation miscalculated; data were excluded from statistical analysis.
- e* No litter observed; however, implantation sites were present at necropsy. Data were excluded from statistical analysis.

Abbreviations

--- = No Data

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				
646653	276.7	321.8	364.6	465.2
646575	348.3	345.9	388.8	452.1
646585 ^a	282.0	295.1	302.5	308.0
646622	355.3	387.3	422.6	516.8
646550	360.2	382.8	417.2	480.4
646526	282.0	337.1	374.7	458.5
646503	289.7	329.1	359.0	465.9
646644 ^b	---	---	---	---
646604	296.6	333.4	367.2	458.1
646651	312.9	342.2	368.0	464.9
646552 ^a	302.4	300.8	317.7	333.3
646606	255.8	289.6	319.4	407.0
646557	299.0	333.1	366.2	415.7
646591	278.3	314.1	348.5	443.3
646544	316.3	354.9	395.5	496.9
646646	317.3	357.3	395.7	497.3
646520 ^a	251.3	277.6	291.1	290.3
646569	320.1	348.4	380.2	486.3
646654	301.3	332.8	363.0	461.3
646668	342.4	381.3	415.3	491.7

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				
646638	305.5	341.9	392.7	501.4
646559	310.7	350.0	372.7	468.6
646598 ^a	358.5	375.4	388.4	389.6
646561	308.8	348.9	375.5	437.6
646573 ^a	308.8	346.4	359.3	347.6
646504	287.5	314.5	339.9	428.6
646587 ^a	272.1	274.5	284.6	279.5
646631 ^a	375.2	389.8	392.7	400.0
646529	295.5	332.3	364.1	444.1
646603	297.6	327.5	357.1	428.7
646554 ^a	320.2	340.5	353.4	342.6
646579	275.9	313.1	342.3	426.4
646564 ^a	310.7	323.8	331.8	332.9
646672	321.6	365.9	397.0	492.6
646584 ^a	302.7	318.1	323.4	320.8
646543	286.0	301.6	335.1	387.4
646596	285.6	311.2	351.7	431.4
646558 ^a	301.9	325.1	322.6	330.9
646670 ^a	345.1	329.9	344.8	340.2
646553	316.0	346.5	374.7	451.5

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				
646547	296.4	335.9	373.7	489.0
646666 ^a	372.3	364.4	373.2	371.8
646607	303.0	366.9	381.8	492.2
646524 ^c	---	---	---	---
646600	300.2	339.5	372.9	470.8
646648	273.5	294.8	325.8	391.9
646594	290.8	322.8	378.0	452.3
646546	287.2	313.7	343.6	441.2
646661 ^a	303.7	333.8	337.6	344.6
646671	296.5	338.4	366.3	454.4
646521	293.3	320.7	343.5	390.6
646590 ^a	294.5	316.0	334.5	338.1
646645	266.9	299.7	335.8	410.4
646555 ^a	314.7	334.1	334.3	337.0
646605 ^a	291.3	325.5	329.5	326.7
646589 ^a	243.1	245.0	254.6	257.3
646615	292.0	317.6	346.9	438.1
646527 ^a	305.8	315.2	316.4	316.2
646647	303.1	326.0	351.9	461.4
646675 ^a	316.6	322.3	325.0	323.1

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

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

GESTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
646662	242.9	264.2	293.9	352.7
646583 ^a	287.1	317.9	334.2	325.3
646623	279.1	323.8	338.4	401.4
646619	312.0	338.0	372.1	446.8
646539	324.5	341.0	380.1	464.5
646628 ^a	278.7	315.4	323.3	315.1
646616 ^a	291.4	311.5	321.6	309.9
646563 ^a	290.8	299.4	301.2	303.5
646641	305.5	343.2	376.7	450.3
646572	237.0	272.4	293.8	333.4
646512	284.0	298.6	298.0	297.4
646566	273.1	283.4	319.9	383.9
646570 ^a	269.2	283.3	311.4	386.2
646602	274.7	298.1	313.5	351.2
646582 ^a	298.5	293.4	301.3	303.0
646655	291.1	313.0	339.8	415.3
646663 ^d	294.9	323.3	384.5	---
646640 ^e	292.7	304.8	326.2	264.2
646574	296.3	324.7	360.0	424.4
646532	288.7	323.3	355.3	440.0

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 was delivered; data were excluded from statistical analysis.
- b* No gestation data were collected since no copulation plug was observed; however a litter was delivered.
- c* No gestation data were collected since no copulation plug was observed; no litter was delivered.
- d* Start of gestation miscalculated; data were excluded from statistical analysis.
- e* No litter observed; however, implantation sites were present at necropsy. Data were excluded from statistical analysis.

Abbreviations

--- = No Data

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				
646653	45.1	42.8	100.6	188.5
646575	-2.4	42.9	63.3	103.8
646585 ^a	13.1	7.4	5.5	26.0
646622	32.0	35.3	94.2	161.5
646550	22.6	34.4	63.2	120.2
646526	55.1	37.6	83.8	176.5
646503	39.4	29.9	106.9	176.2
646644 ^b	---	---	---	---
646604	36.8	33.8	90.9	161.5
646651	29.3	25.8	96.9	152.0
646552 ^a	-1.6	16.9	15.6	30.9
646606	33.8	29.8	87.6	151.2
646557	34.1	33.1	49.5	116.7
646591	35.8	34.4	94.8	165.0
646544	38.6	40.6	101.4	180.6
646646	40.0	38.4	101.6	180.0
646520 ^a	26.3	13.5	-0.8	39.0
646569	28.3	31.8	106.1	166.2
646654	31.5	30.2	98.3	160.0
646668	38.9	34.0	76.4	149.3

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				
646638	36.4	50.8	108.7	195.9
646559	39.3	22.7	95.9	157.9
646598 ^a	16.9	13.0	1.2	31.1
646561	40.1	26.6	62.1	128.8
646573 ^a	37.6	12.9	-11.7	38.8
646504	27.0	25.4	88.7	141.1
646587 ^a	2.4	10.1	-5.1	7.4
646631 ^a	14.6	2.9	7.3	24.8
646529	36.8	31.8	80.0	148.6
646603	29.9	29.6	71.6	131.1
646554 ^a	20.3	12.9	-10.8	22.4
646579	37.2	29.2	84.1	150.5
646564 ^a	13.1	8.0	1.1	22.2
646672	44.3	31.1	95.6	171.0
646584 ^a	15.4	5.3	-2.6	18.1
646543	15.6	33.5	52.3	101.4
646596	25.6	40.5	79.7	145.8
646558 ^a	23.2	-2.5	8.3	29.0
646670 ^a	-15.2	14.9	-4.6	-4.9
646553	30.5	28.2	76.8	135.5

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				
646547	39.5	37.8	115.3	192.6
646666 ^a	-7.9	8.8	-1.4	-0.5
646607	63.9	14.9	110.4	189.2
646524 ^c	---	---	---	---
646600	39.3	33.4	97.9	170.6
646648	21.3	31.0	66.1	118.4
646594	32.0	55.2	74.3	161.5
646546	26.5	29.9	97.6	154.0
646661 ^a	30.1	3.8	7.0	40.9
646671	41.9	27.9	88.1	157.9
646521	27.4	22.8	47.1	97.3
646590 ^a	21.5	18.5	3.6	43.6
646645	32.8	36.1	74.6	143.5
646555 ^a	19.4	0.2	2.7	22.3
646605 ^a	34.2	4.0	-2.8	35.4
646589 ^a	1.9	9.6	2.7	14.2
646615	25.6	29.3	91.2	146.1
646527 ^a	9.4	1.2	-0.2	10.4
646647	22.9	25.9	109.5	158.3
646675 ^a	5.7	2.7	-1.9	6.5

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

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
646662	21.3	29.7	58.8	109.8
646583 ^a	30.8	16.3	-8.9	38.2
646623	44.7	14.6	63.0	122.3
646619	26.0	34.1	74.7	134.8
646539	16.5	39.1	84.4	140.0
646628 ^a	36.7	7.9	-8.2	36.4
646616 ^a	20.1	10.1	-11.7	18.5
646563 ^a	8.6	1.8	2.3	12.7
646641	37.7	33.5	73.6	144.8
646572	35.4	21.4	39.6	96.4
646512	14.6	-0.6	-0.6	13.4
646566	10.3	36.5	64.0	110.8
646570 ^a	14.1	28.1	74.8	117.0
646602	23.4	15.4	37.7	76.5
646582 ^a	-5.1	7.9	1.7	4.5
646655	21.9	26.8	75.5	124.2
646663 ^d	28.4	61.2	---	---
646640 ^e	12.1	21.4	-62.0	-28.5
646574	28.4	35.3	64.4	128.1
646532	34.6	32.0	84.7	151.3

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 was delivered; therefore no lactation data were collected.
- b* No data due to weighing error.
- c* All pups were found dead on Lactation Day 0. Data were excluded from statistical analysis.

Abbreviations

--- = No Data

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				
646653	325.0	354.1	371.6	357.9
646575	361.4	383.8	401.0	375.5
646585 ^a	---	---	---	---
646622	383.0	393.2	417.6	388.5
646550	340.4	343.4	355.8	361.8
646526	367.8	368.2	384.3	348.3
646503	332.5	351.7	380.7	350.9
646644	323.2	356.8	359.3	277.7
646604	337.0	358.1	388.2	371.9
646651	--- ^b	358.4	376.2	351.9
646552 ^a	---	---	---	---
646606	309.2	297.9	332.9	313.7
646557	342.2	333.3	360.4	339.0
646591	322.0	335.8	360.1	324.6
646544	374.8	375.8	382.3	359.8
646646	368.5	386.1	396.1	361.2
646520 ^a	---	---	---	---
646569	361.3	368.3	386.9	368.7
646654	346.0	354.1	379.3	356.5
646668	390.9	393.7	429.5	392.2

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				
646638	365.8	368.5	375.7	363.4
646559	353.8	357.0	365.6	339.2
646598 ^a	---	---	---	---
646561	369.3	379.0	381.6	361.1
646573 ^a	---	---	---	---
646504	303.2	331.6	369.3	360.6
646587 ^a	---	---	---	---
646631 ^a	---	---	---	---
646529	350.0	348.4	356.4	350.1
646603	325.0	359.9	348.0	354.0
646554 ^a	---	---	---	---
646579	305.1	323.8	340.4	287.4
646564 ^a	---	---	---	---
646672	379.0	388.0	389.2	376.8
646584 ^a	---	---	---	---
646543	--- ^b	329.5	341.1	325.3
646596	314.6	328.1	353.5	341.5
646558 ^a	---	---	---	---
646670 ^a	---	---	---	---
646553	373.9	376.9	390.4	303.7

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				
646547	351.1	372.7	368.1	342.3
646666 ^a	---	---	---	---
646607	367.2	371.3	378.9	375.3
646524 ^a	---	---	---	---
646600	324.6	355.5	380.4	362.2
646648	315.8	348.6	351.8	312.7
646594	341.9	356.9	345.8	364.7
646546	315.9	340.1	365.6	352.4
646661 ^a	---	---	---	---
646671	321.8	323.0	338.0	350.0
646521	306.6	351.9	375.7	373.1
646590 ^a	---	---	---	---
646645	300.2	334.7	355.2	351.6
646555 ^a	---	---	---	---
646605 ^a	---	---	---	---
646589 ^a	---	---	---	---
646615	334.1	318.1	304.0	348.4
646527 ^a	---	---	---	---
646647	332.0	354.4	364.8	344.0
646675 ^a	---	---	---	---

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

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

LACTATION DAYS:	0	7	14	21
ANIMAL NUMBER				
646662	261.0	288.0	291.1	287.1
646583 ^a	---	---	---	---
646623	335.6	327.3	355.8	357.3
646619	345.3	340.6	351.5	356.3
646539	375.4	373.6	389.5	406.7
646628 ^a	---	---	---	---
646616 ^a	---	---	---	---
646563 ^a	---	---	---	---
646641	346.1	368.7	376.5	374.4
646572	291.3	296.5	300.9	305.7
646512	275.8	299.3	327.4	327.7
646566	286.2	318.8	318.3	317.6
646570 ^a	---	---	---	---
646602	286.5	314.9	309.8	293.3
646582 ^a	---	---	---	---
646655	309.4	325.5	331.5	303.0
646663	292.1	311.8	332.1	336.2
646640 ^a	---	---	---	---
646574 ^c	303.4	340.8	333.7	335.3
646532	331.2	361.4	340.7	347.3

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 was delivered; therefore no lactation data were collected.
- b* No data due to weighing error.
- c* All pups were found dead on Lactation Day 0. Data were excluded from statistical analysis.

Abbreviations

--- = No Data

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				
646653	29.1	17.5	-13.7	32.9
646575	22.4	17.2	-25.5	14.1
646585 ^a	---	---	---	---
646622	10.2	24.4	-29.1	5.5
646550	3.0	12.4	6.0	21.4
646526	0.4	16.1	-36.0	-19.5
646503	19.2	29.0	-29.8	18.4
646644	33.6	2.5	-81.6	-45.5
646604	21.1	30.1	-16.3	34.9
646651	--- ^b	17.8	-24.3	--- ^b
646552 ^a	---	---	---	---
646606	-11.3	35.0	-19.2	4.5
646557	-8.9	27.1	-21.4	-3.2
646591	13.8	24.3	-35.5	2.6
646544	1.0	6.5	-22.5	-15.0
646646	17.6	10.0	-34.9	-7.3
646520 ^a	---	---	---	---
646569	7.0	18.6	-18.2	7.4
646654	8.1	25.2	-22.8	10.5
646668	2.8	35.8	-37.3	1.3

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				
646638	2.7	7.2	-12.3	-2.4
646559	3.2	8.6	-26.4	-14.6
646598 ^a	---	---	---	---
646561	9.7	2.6	-20.5	-8.2
646573 ^a	---	---	---	---
646504	28.4	37.7	-8.7	57.4
646587 ^a	---	---	---	---
646631 ^a	---	---	---	---
646529	-1.6	8.0	-6.3	0.1
646603	34.9	-11.9	6.0	29.0
646554 ^a	---	---	---	---
646579	18.7	16.6	-53.0	-17.7
646564 ^a	---	---	---	---
646672	9.0	1.2	-12.4	-2.2
646584 ^a	---	---	---	---
646543	--- ^b	11.6	-15.8	--- ^b
646596	13.5	25.4	-12.0	26.9
646558 ^a	---	---	---	---
646670 ^a	---	---	---	---
646553	3.0	13.5	-86.7	-70.2

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				
646547	21.6	-4.6	-25.8	-8.8
646666 ^a	---	---	---	---
646607	4.1	7.6	-3.6	8.1
646524 ^a	---	---	---	---
646600	30.9	24.9	-18.2	37.6
646648	32.8	3.2	-39.1	-3.1
646594	15.0	-11.1	18.9	22.8
646546	24.2	25.5	-13.2	36.5
646661 ^a	---	---	---	---
646671	1.2	15.0	12.0	28.2
646521	45.3	23.8	-2.6	66.5
646590 ^a	---	---	---	---
646645	34.5	20.5	-3.6	51.4
646555 ^a	---	---	---	---
646605 ^a	---	---	---	---
646589 ^a	---	---	---	---
646615	-16.0	-14.1	44.4	14.3
646527 ^a	---	---	---	---
646647	22.4	10.4	-20.8	12.0
646675 ^a	---	---	---	---

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

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

LACTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
646662	27.0	3.1	-4.0	26.1
646583 ^a	---	---	---	---
646623	-8.3	28.5	1.5	21.7
646619	-4.7	10.9	4.8	11.0
646539	-1.8	15.9	17.2	31.3
646628 ^a	---	---	---	---
646616 ^a	---	---	---	---
646563 ^a	---	---	---	---
646641	22.6	7.8	-2.1	28.3
646572	5.2	4.4	4.8	14.4
646512	23.5	28.1	0.3	51.9
646566	32.6	-0.5	-0.7	31.4
646570 ^a	---	---	---	---
646602	28.4	-5.1	-16.5	6.8
646582 ^a	---	---	---	---
646655	16.1	6.0	-28.5	-6.4
646663	19.7	20.3	4.1	44.1
646640 ^a	---	---	---	---
646574 ^c	37.4	-7.1	1.6	31.9
646532	30.2	-20.7	6.6	16.1

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 was delivered; data were excluded from statistical analysis.
- b* No gestation data were collected since no copulation plug was observed; however a litter was delivered.
- c* No gestation data were collected since no copulation plug was observed; no litter was delivered.
- d* Start of gestation miscalculated; data were excluded from statistical analysis.
- e* No litter observed; however, implantation sites were present at necropsy. Data were excluded from statistical analysis.

Abbreviations

--- = No Data

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				
646653	26.1	28.5	31.0	28.5
646575	19.5	30.4	29.3	26.4
646585 ^a	21.0	19.1	20.0	20.0
646622	25.8	28.9	17.0	23.9
646550	25.0	27.1	24.7	25.6
646526	27.5	26.1	27.8	27.1
646503	25.3	27.0	27.0	26.4
646644 ^b	---	---	---	---
646604	24.5	27.5	28.2	26.7
646651	24.9	23.7	24.6	24.4
646552 ^a	19.1	21.1	21.1	20.4
646606	21.8	23.6	23.4	23.0
646557	24.9	29.0	28.5	27.5
646591	24.5	20.7	29.3	24.9
646544	29.9	32.7	30.1	30.9
646646	27.5	29.4	31.3	29.4
646520 ^a	21.0	22.1	21.7	21.6
646569	26.1	28.0	29.5	27.9
646654	25.3	25.4	26.9	25.9
646668	24.9	27.4	27.7	26.7

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				
646638	25.4	30.6	32.3	29.4
646559	25.5	25.0	29.0	26.5
646598 ^a	27.0	26.5	25.0	26.1
646561	27.7	27.7	28.3	27.9
646573 ^a	27.4	28.2	24.3	26.6
646504	21.9	22.9	23.8	22.9
646587 ^a	19.5	19.9	18.4	19.3
646631 ^a	25.4	25.6	26.0	25.7
646529	23.3	25.7	27.8	25.6
646603	9.6	24.6	24.1	19.4
646554 ^a	21.6	21.3	12.0	18.3
646579	25.5	26.2	26.2	26.0
646564 ^a	21.3	20.0	18.5	19.9
646672	27.4	29.1	30.2	28.9
646584 ^a	6.6	24.6	18.5	16.6
646543	22.2	37.3	27.0	28.8
646596	23.8	25.5	26.0	25.1
646558 ^a	22.9	20.1	20.2	21.1
646670 ^a	22.8	19.7	20.1	20.9
646553	31.5	27.4	30.9	29.9

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				
646547	28.7	31.1	36.0	32.0
646666 ^a	24.0	22.6	25.0	23.9
646607	29.2	28.7	34.0	30.7
646524 ^c	---	---	---	---
646600	26.1	26.6	28.3	27.0
646648	22.2	22.4	27.3	23.9
646594	25.4	28.6	33.3	29.1
646546	18.2	24.5	28.0	23.6
646661 ^a	26.3	23.7	23.1	24.4
646671	25.6	27.5	29.5	27.5
646521	23.3	23.8	24.3	23.8
646590 ^a	22.8	24.9	19.9	22.5
646645	24.3	25.1	27.5	25.6
646555 ^a	27.3	25.3	18.0	23.5
646605 ^a	26.0	26.2	20.0	24.1
646589 ^a	18.2	20.1	25.2	21.2
646615	24.5	27.6	31.2	27.8
646527 ^a	22.1	20.1	20.0	20.7
646647	22.6	23.4	7.6	17.8
646675 ^a	20.6	22.8	23.3	22.2

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

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

GESTATION DAYS:	0-7	7-14	14-21	0-21
ANIMAL NUMBER				
646662	18.3	21.3	22.8	20.8
646583 ^a	21.0	23.5	20.9	21.8
646623	25.5	28.5	28.7	27.6
646619	27.0	30.9	32.4	30.1
646539	21.7	28.4	18.5	22.9
646628 ^a	25.5	26.4	24.3	25.4
646616 ^a	25.3	4.8	23.0	17.7
646563 ^a	22.9	22.3	36.6	27.2
646641	26.5	27.4	32.3	28.7
646572	22.1	22.4	24.7	23.1
646512	23.0	20.7	21.0	21.6
646566	18.6	25.5	28.6	24.3
646570 ^a	17.9	20.2	26.5	21.5
646602	25.6	25.8	27.5	26.3
646582 ^a	19.3	21.6	20.0	20.3
646655	19.3	25.4	29.7	24.8
646663 ^d	24.9	24.3	---	---
646640 ^e	25.5	28.3	10.0	21.3
646574	26.8	31.2	31.5	29.9
646532	26.4	31.4	34.5	30.7

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
646490	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646440	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646424	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646402	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646392	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646473	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646395	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646352	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646357	DISCHARGE NOSE RED DISCHARGE MOUTH RED SACRIFICED BY DESIGN TEST DAY 103	78 78	98 78
646409	ALOPECIA RIGHT FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 103	84	103
646328	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		
646479	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		
646470	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646461	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		
646480	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		
646383	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		
646445	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		
646358	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		
646425	DISCHARGE EYE(S) RED STAINED RIGHT EYE(S) BROWN SACRIFICED BY DESIGN TEST DAY 105	84 91	84 91
646408	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646378	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646483	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646363	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646334	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646493	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646404	SALIVATION SACRIFICED BY DESIGN TEST DAY 103	95	95
646415	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646410	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646340	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646354	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646467	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646381	SALIVATION SALIVATION SALIVATION SACRIFICED BY DESIGN TEST DAY 104	84 95 100	89 95 100
646342	SALIVATION SACRIFICED BY DESIGN TEST DAY 104	100	100

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646450	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		
646326	SALIVATION SACRIFICED BY DESIGN TEST DAY 104	100	100
646377	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		
646478	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		
646350	ALOPECIA BOTH FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 105	84	105
646333	SALIVATION SACRIFICED BY DESIGN TEST DAY 105	100	100
646486	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 105		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646353	SALIVATION SACRIFICED BY DESIGN TEST DAY 102	100	100
646341	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S) SALIVATION SACRIFICED BY DESIGN TEST DAY 102	84 84 100	102 102 100
646356	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646330	SALIVATION SALIVATION SACRIFICED BY DESIGN TEST DAY 102	90 101	90 101
646499	ALOPECIA BOTH FRONT LEG(S) ALOPECIA RIGHT FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 102	84 84	102 102
646400	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 103	84	103
646417	SALIVATION SACRIFICED BY DESIGN TEST DAY 103	100	100
646338	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 103		
646394	SALIVATION SALIVATION SALIVATION SACRIFICED BY DESIGN TEST DAY 103	79 92 100	90 96 102
646387	SALIVATION SACRIFICED BY DESIGN TEST DAY 103	101	101
646447	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 104		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646336	SALIVATION	89	89
	SALIVATION	100	100
	SACRIFICED BY DESIGN TEST DAY 104		
646366	SALIVATION	85	85
	SACRIFICED BY DESIGN TEST DAY 104		
646496	SALIVATION	89	98
	SACRIFICED BY DESIGN TEST DAY 104		
646375	SALIVATION	96	99
	SACRIFICED BY DESIGN TEST DAY 104		
646465	SALIVATION	98	98
	SACRIFICED BY DESIGN TEST DAY 105		
646390	SALIVATION	92	95
	SACRIFICED BY DESIGN TEST DAY 105		
646429	SALIVATION	81	95
	SALIVATION	101	101
	SACRIFICED BY DESIGN TEST DAY 105		
646476	SALIVATION	89	91
	SACRIFICED BY DESIGN TEST DAY 105		
646348	SALIVATION	83	89
	SALIVATION	99	99
	SACRIFICED BY DESIGN TEST DAY 105		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: VII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646382	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646406	SALIVATION SACRIFICED BY DESIGN TEST DAY 102	97	97
646491	SALIVATION SACRIFICED BY DESIGN TEST DAY 102	99	99
646351	SALIVATION SACRIFICED BY DESIGN TEST DAY 102	78	100
646405	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 102		
646418	SALIVATION SACRIFICED BY DESIGN TEST DAY 103	99	99
646362	ALOPECIA INGUEN ALOPECIA PERINEUM SALIVATION SACRIFICED BY DESIGN TEST DAY 103	81 81 81	103 103 84
646497	STAINED INGUEN YELLOW STAINED PERINEUM YELLOW SALIVATION SALIVATION SACRIFICED BY DESIGN TEST DAY 103	78 78 78 96	96 98 82 96
646401	SALIVATION SALIVATION SACRIFICED BY DESIGN TEST DAY 103	78 92	89 102
646498	ALOPECIA RIGHT FRONT LEG(S) ALOPECIA RIGHT FRONT PAW(S) ALOPECIA BOTH FRONT PAW(S) ALOPECIA BOTH FRONT LEG(S) STAINED PERINEUM YELLOW SACRIFICED BY DESIGN TEST DAY 103	84 84 91 91 98	84 84 103 103 103

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ MALE RATS

GROUP: VII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646386	SALIVATION	89	89
	SALIVATION	102	102
	STAINED PERINEUM YELLOW	104	104
	SACRIFICED BY DESIGN TEST DAY 104		
646332	SALIVATION	80	80
	SALIVATION	90	90
	SALIVATION	95	95
	SALIVATION	99	99
	SACRIFICED BY DESIGN TEST DAY 104		
646441	SALIVATION	85	89
	SALIVATION	98	102
	SACRIFICED BY DESIGN TEST DAY 104		
646452	SALIVATION	82	82
	SALIVATION	85	85
	SALIVATION	99	99
	SACRIFICED BY DESIGN TEST DAY 104		
646365	STAINED PERINEUM YELLOW	91	104
	SACRIFICED BY DESIGN TEST DAY 104		
646393	SALIVATION	82	82
	SALIVATION	92	98
	SACRIFICED BY DESIGN TEST DAY 105		
646359	ALOPECIA BOTH FRONT LEG(S)	84	90
	ALOPECIA BOTH FRONT PAW(S)	84	105
	SALIVATION	84	90
	SALIVATION	92	96
	SALIVATION	99	104
	SACRIFICED BY DESIGN TEST DAY 105		
646451	SALIVATION	89	89
	SALIVATION	96	96
	SALIVATION	100	100
	SACRIFICED BY DESIGN TEST DAY 105		

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

Note

This appendix includes only clinical observations from rats with copulation plug observed.

Footnotes

- a* Copulation plug observed but no litter delivered.
- b* Delivered a litter on Day 16G.

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
646653	DISCHARGE LEFT EYE(S) RED	7	21
646575	NO ABNORMALITIES DETECTED		
646585 ^a	NO ABNORMALITIES DETECTED		
646622	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S)	0 0	21 21
646550	NO ABNORMALITIES DETECTED		
646526	NO ABNORMALITIES DETECTED		
646503	NO ABNORMALITIES DETECTED		
646604	NO ABNORMALITIES DETECTED		
646651	NO ABNORMALITIES DETECTED		
646552 ^a	NO ABNORMALITIES DETECTED		
646606	ALOPECIA LEFT FRONT LEG(S) ALOPECIA BOTH FRONT LEG(S)	0 7	0 21
646557	NO ABNORMALITIES DETECTED		
646591	ALOPECIA BACK	0	7
646544	NO ABNORMALITIES DETECTED		
646646	NO ABNORMALITIES DETECTED		
646520 ^a	NO ABNORMALITIES DETECTED		
646569	NO ABNORMALITIES DETECTED		
646654	NO ABNORMALITIES DETECTED		
646668	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
646638	NO ABNORMALITIES DETECTED		
646559	NO ABNORMALITIES DETECTED		
646598 ^a	STAINED PERINEUM YELLOW	0	0
646561	NO ABNORMALITIES DETECTED		
646573 ^a	NO ABNORMALITIES DETECTED		
646504	ALOPECIA BOTH FRONT PAW(S)	21	21
646587 ^a	NO ABNORMALITIES DETECTED		
646631 ^a	ALOPECIA RIGHT FRONT LEG(S) ALOPECIA RIGHT FRONT PAW(S)	0 0	21 21
646529	NO ABNORMALITIES DETECTED		
646603	ALOPECIA BOTH FRONT PAW(S)	0	21
646554 ^a	NO ABNORMALITIES DETECTED		
646579	NO ABNORMALITIES DETECTED		
646564 ^a	NO ABNORMALITIES DETECTED		
646672	NO ABNORMALITIES DETECTED		
646584 ^a	NO ABNORMALITIES DETECTED		
646543	NO ABNORMALITIES DETECTED		
646596	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S) ALOPECIA RIGHT SIDE(S)	0 0 21	21 21 21
646558 ^a	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
646670 ^a	ALOPECIA BOTH FRONT LEG(S)	0	21
	STAINED PERINEUM YELLOW	7	7
	ALOPECIA BOTH FRONT PAW(S)	18	21
646553	ALOPECIA RIGHT FRONT LEG(S)	0	14
	ALOPECIA RIGHT FRONT PAW(S)	0	14
	ALOPECIA BOTH FRONT PAW(S)	18	21

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
646547	SALIVATION	2	7
646666 ^a	NO ABNORMALITIES DETECTED		
646607	SALIVATION	4	4
646600	SALIVATION	6	7
646648	SALIVATION SALIVATION	5 18	5 18
646594	NO ABNORMALITIES DETECTED		
646546	ALOPECIA BOTH HIND QUARTERS ALOPECIA RIGHT SIDE(S)	18 18	21 21
646661 ^a	SALIVATION	15	15
646671	STAINED PERINEUM BROWN	14	14
646521	ALOPECIA BOTH FRONT LEG(S)	0	21
646590 ^a	SALIVATION SALIVATION	5 15	5 18
646645	NO ABNORMALITIES DETECTED		
646555 ^a	NO ABNORMALITIES DETECTED		
646605 ^a	SALIVATION SALIVATION	5 16	5 16
646589 ^a	SALIVATION	16	16
646615	SALIVATION ALOPECIA BOTH HIND QUARTERS	4 14	7 21
646527 ^a	NO ABNORMALITIES DETECTED		
646647	NO ABNORMALITIES DETECTED		
646675 ^a	NO ABNORMALITIES DETECTED		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646662	SALIVATION	6	6
646583 ^a	NO ABNORMALITIES DETECTED		
646623	SALIVATION	16	17
646619	NO ABNORMALITIES DETECTED		
646539	NO ABNORMALITIES DETECTED		
646628 ^a	SALIVATION	15	19
	STAINED PERINEUM YELLOW	18	19
646616 ^a	SALIVATION	5	11
646563 ^a	SALIVATION	16	16
	SALIVATION	19	19
646641	NO ABNORMALITIES DETECTED		
646572	ALOPECIA ABDOMEN	0	7
	ALOPECIA CHEST	0	7
	ALOPECIA UNDERBODY	14	21
	ALOPECIA BOTH HIND QUARTERS	14	21
	ALOPECIA BOTH SIDE(S)	18	21
646512	ALOPECIA BOTH REAR LEG(S)	0	21
	ALOPECIA ABDOMEN	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA PERINEUM	7	21
	ALOPECIA BOTH FRONT LEG(S)	14	21
	ALOPECIA BOTH SIDE(S)	14	21
646566	NO ABNORMALITIES DETECTED		
646570 ^a	ALOPECIA RIGHT SIDE(S)	18	21
	ALOPECIA BOTH FRONT PAW(S)	18	21
	ALOPECIA ABDOMEN	21	21

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING GESTATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646602	ALOPECIA ABDOMEN	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA LEFT SHOULDER(S)	0	21
	SALIVATION	4	4
	SALIVATION	15	17
646582 ^a	STAINED PERINEUM YELLOW	0	21
646655	ALOPECIA BOTH FRONT PAW(S)	0	0
	STAINED PERINEUM YELLOW	7	18
646663 ^b	SALIVATION	0	0
	STAINED PERINEUM YELLOW	14	14
646640 ^a	STAINED PERINEUM YELLOW	0	16
	COLOR DISCHARGE VAGINAL OPENING RED	16	16
	STAINED CAGEBOARD RED	16	16
	STAINED VAGINAL OPENING BROWN	18	18
	COLOR DISCHARGE VAGINAL OPENING RED	21	21
646574	ALOPECIA RIGHT HIND QUARTERS	7	7
	ALOPECIA BOTH HIND QUARTERS	14	21
	ALOPECIA PERINEUM	14	21
646532	ALOPECIA UNDERBODY	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA BOTH SIDE(S)	0	21
	ALOPECIA BOTH FRONT LEG(S)	0	21
	ALOPECIA BOTH FRONT PAW(S)	0	21

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

Note

This appendix includes clinical observations from lactating rats only.

Footnote

a No copulation plug was observed, however, a litter was delivered.

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
646653	DISCHARGE LEFT EYE(S) RED STAINED LEFT EYE(S) BROWN SACRIFICED BY DESIGN TEST DAY 119	0 21	14 21
646575	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 119		
646622	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 125	0 0	7 21
646550	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 127		
646526	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646503	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646644 ^a	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 117		
646604	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 122		
646651	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646606	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 119	0 7	21 21
646557	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646591	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646544	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		

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
646646	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646569	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646654	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646668	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		

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
646638	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646559	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646561	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646504	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 118	0	21
646529	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646603	ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 119	0	21
646579	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 117		
646672	MASS 1 2.0 cm LEFT SHOULDER(S) SACRIFICED BY DESIGN TEST DAY 119	2	21
646543	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646596	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH FRONT PAW(S) ALOPECIA RIGHT SIDE(S) ALOPECIA RIGHT REAR LEG(S) SACRIFICED BY DESIGN TEST DAY 118	0 0 0 7	21 21 0 21
646553	ALOPECIA BOTH FRONT PAW(S) ALOPECIA BOTH FRONT LEG(S) SACRIFICED BY DESIGN TEST DAY 122	0 21	21 21

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
646547	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646607	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 120		
646600	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646648	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 117		
646594	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646546	ALOPECIA BOTH HIND QUARTERS ALOPECIA RIGHT SIDE(S) SACRIFICED BY DESIGN TEST DAY 118	0 0	21 21
646671	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 121		
646521	ALOPECIA BOTH FRONT LEG(S) ALOPECIA BOTH REAR LEG(S) ALOPECIA LEFT SIDE(S) SACRIFICED BY DESIGN TEST DAY 121	0 0 14	21 21 21
646645	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646615	ALOPECIA BOTH HIND QUARTERS ALOPECIA ABDOMEN SALIVATION SACRIFICED BY DESIGN TEST DAY 121	0 0 5	21 5 5
646647	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 124		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646662	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 119		
646623	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646619	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646539	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646641	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 118		
646572	ALOPECIA UNDERBODY	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA BOTH SIDE(S)	0	21
	SACRIFICED BY DESIGN TEST DAY 118		
646512	ALOPECIA BOTH REAR LEG(S)	0	21
	ALOPECIA ABDOMEN	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA PERINEUM	0	21
	ALOPECIA BOTH FRONT LEG(S)	0	21
	ALOPECIA BOTH SIDE(S)	0	21
	SACRIFICED BY DESIGN TEST DAY 117		
646566	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 119		
646602	ALOPECIA ABDOMEN	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA LEFT SHOULDER(S)	0	21
	STAINED PERINEUM YELLOW	21	21
	SACRIFICED BY DESIGN TEST DAY 119		
646655	STAINED PERINEUM YELLOW	0	7
	SACRIFICED BY DESIGN TEST DAY 121		

INDIVIDUAL CLINICAL OBSERVATIONS IN P₁ FEMALE RATS DURING LACTATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
646663	COLORED DISCHARGE VAGINAL OPENING RED SACRIFICED BY DESIGN TEST DAY 121	0	0
646532	ALOPECIA UNDERBODY	0	21
	ALOPECIA BOTH HIND QUARTERS	0	21
	ALOPECIA BOTH SIDE(S)	0	21
	ALOPECIA BOTH FRONT LEG(S)	0	21
	ALOPECIA BOTH FRONT PAW(S)	0	21
	SACRIFICED BY DESIGN TEST DAY 122		

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* Copulation plug detected, but animal did not deliver a litter.
- b* Mean cycle length was not calculable due to insufficient data.
- c* No evidence of copulation was found; but animal did deliver a litter. Animal was excluded from group summary data.
- d* No precoital interval could be calculated since no evidence of copulation was found.
- e* No evidence of copulation was found; animal did not deliver a litter.
- f* Animal delivered a litter on Day 16G. Animal was excluded from statistical analyses.

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)
646653	22	23%	68%	9%	4.67	2
646575	22	36%	59%	5%	4.50	2
646585 ^a	21	33%	67%	0%	4.00	1
646622	29	14%	79%	7%	5.50	9
646550	30	53%	43%	3%	---b	10
646526	21	52%	33%	14%	---b	1
646503	21	19%	67%	14%	4.00	1
646644 ^c	35	20%	74%	6%	5.33	---d
646604	26	23%	69%	8%	4.00	6
646651	21	24%	76%	0%	4.00	1
646552 ^a	21	33%	57%	10%	4.00	1
646606	23	22%	65%	13%	4.00	3
646557	23	22%	78%	0%	4.00	3
646591	24	25%	58%	17%	4.75	4
646544	21	100%	0%	0%	---b	1
646646	22	23%	73%	5%	4.00	2
646520 ^a	26	27%	69%	4%	4.00	6
646569	24	29%	58%	13%	4.00	4
646654	24	33%	58%	8%	4.00	4
646668	23	22%	70%	9%	5.00	3

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)
646638	22	32%	59%	9%	4.00	2
646559	21	33%	62%	5%	5.00	1
646598 ^a	31	55%	32%	13%	4.67	11
646561	21	24%	71%	5%	4.33	1
646573 ^a	21	81%	14%	5%	---b	1
646504	22	23%	73%	5%	4.00	2
646587 ^a	21	29%	57%	14%	6.33	2
646631 ^a	26	23%	73%	4%	5.25	6
646529	22	9%	82%	9%	4.67	2
646603	22	23%	68%	9%	4.00	3
646554 ^a	29	14%	83%	3%	5.75	9
646579	21	33%	48%	19%	4.00	1
646564 ^a	26	19%	69%	12%	5.00	6
646672	22	14%	73%	14%	3.75	2
646584 ^a	24	25%	71%	4%	4.00	4
646543	21	95%	0%	5%	---b	1
646596	22	23%	59%	18%	5.00	2
646558 ^a	21	24%	57%	19%	5.00	1
646670 ^a	22	18%	68%	14%	5.00	3
646553	26	27%	65%	8%	4.50	6

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)
646547	24	29%	58%	13%	4.50	4
646666a	24	21%	75%	4%	3.60	4
646607	23	22%	70%	9%	4.25	3
646524e	35	66%	34%	0%	6.67	---d
646600	22	27%	68%	5%	4.25	2
646648	21	19%	71%	10%	5.00	1
646594	22	27%	64%	9%	4.00	2
646546	22	32%	68%	0%	4.25	2
646661a	20	50%	45%	5%	6.00	1
646671	24	29%	67%	4%	4.75	4
646521	24	25%	71%	4%	4.00	4
646590a	21	43%	57%	0%	8.00	1
646645	21	38%	57%	5%	6.00	1
646555a	21	100%	0%	0%	---b	1
646605a	21	10%	90%	0%	---b	1
646589a	20	35%	45%	20%	4.00	1
646615	24	21%	71%	8%	5.00	4
646527a	24	25%	75%	0%	4.25	4
646647	27	26%	70%	4%	5.00	7
646675a	26	38%	46%	15%	4.50	6

INDIVIDUAL ANIMAL ESTROUS CYCLE PARAMETERS
DURING PREMATING AND COHABITATION

GROUP VIII-0: 500 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)
646662	22	23%	68%	9%	5.00	2
646583 ^a	22	23%	64%	14%	5.00	2
646623	21	38%	57%	5%	4.67	1
646619	21	29%	57%	14%	5.00	1
646539	21	24%	62%	14%	5.33	1
646628 ^a	20	25%	60%	15%	5.67	1
646616 ^a	33	58%	39%	3%	5.67	14
646563 ^a	21	14%	67%	19%	4.33	1
646641	21	24%	57%	19%	5.00	1
646572	21	29%	62%	10%	5.33	1
646512	21	29%	57%	14%	5.33	1
646566	22	23%	64%	14%	4.25	2
646570 ^a	21	76%	14%	10%	---b	1
646602	22	14%	73%	14%	4.00	2
646582 ^a	25	32%	68%	0%	5.00	6
646655	24	25%	67%	8%	4.75	4
646663 ^f	31	23%	77%	0%	4.00	11
646640 ^a	29	21%	79%	0%	3.80	9
646574	24	25%	71%	4%	4.00	4
646532	24	29%	63%	8%	5.00	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 52-72 = Premating
Test Days 72-86 = 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 pregnant.
- b* No evidence of copulation was found; animal was not pregnant.
- c* Two females were cohoused one day late (day 77) with two males that had already mated.

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP II-0: 0 MG/KG/DAY

ANIMAL	TEST DAYS																																					
NUMBER	52	53	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			
646653	D	D	P	E	D	D	D	P	E	D	D	D	E	D	D	D	D	E	D	D	D	E																
646575	E	E	D	D	D	E	D	D	D	D	E	D	D	E	D	D	D	D	E	D	D	D																
646585	E	E	D	D	D	D	D	D	D	D	E	D	D	E	D	D	D	D	E	D	D	D																
646622	D	E	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	E									
646550	E	E	D	D	D	D	E	D	D	D	E	D	D	E	D	D	D	E	D	D	E	D	D	D	D	D	D	D	D	E								
646526	E	E	D	D	D	D	E	D	D	D	E	D	D	E	D	D	D	E	D	D	E																	
646503	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D																
646644a	E	D	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			
646604	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								
646651	D	E	D	D	D	D	E	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D								
646552	E	D	D	E	D	D	D	D	E	D	D	D	E	D	D	D	D	D	E	D	D	E																
646606	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								
646557	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								
646591	E	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								
646544	E	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	D	D								
646646	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	D	D								
646520	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	D	D								
646569	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								
646654	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								
646668	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								

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP IV-0: 25 MG/KG/DAY

ANIMAL	TEST DAYS																																					
NUMBER	52	53	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			
646638	E	E	D	D	D	E	D	D	P	E	D	D	D	E	D	D	P	E	D	D	D	E																
646559	D	E	E	D	D	D	E	D	D	D	D	P	E	D	D	D	E	E	D	D	D																	
646598	P	E	D	D	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E			
646561	D	D	E	D	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D																	
646573	E	E	D	D	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D																	
646504	D	D	E	D	D	D	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D	E																
646587	P	E	D	D	D	D	D	D	D	D	X	E	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D				
646631	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	D	D				
646529	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	D	D	D				
646603	D	D	D	E	D	D	D	D	X	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			
646554	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	D	D	D			
646579	D	D	D	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			
646564	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	D	D	D	D			
646672	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	D	D			
646584	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	D	D	D	D			
646543	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	E	E	E	E	E	E	E			
646596	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	D	D	D	D	D	D			
646558	D	D	E	E	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			
646670	E	D	D	D	X	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			
646553	D	D	E	E	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			

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP VI-0: 100 MG/KG/DAY

ANIMAL	TEST DAYS																																				
NUMBER	52	53	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		
646547	D	P	E	D	D	P	E	D	D	P	E	D	D	D	D	P	D	D	D	D	E	D	D	D	E												
646666	D	E	D	D	E	D	D	D	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
646607	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												
646524 ^b	P	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			
646600	E	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
646648	D	D	E	D	D	D	D	D	P	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
646594	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												
646546	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												
646661	E	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	X	D	D	D	D													
646671	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												
646521	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												
646590	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												
646645	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												
646555	E	E	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D												
646605	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												
646589	D	D	P	E	D	D	D	D	D	D	D	X	D	D	D	D	D	D	D	D	D	D	D	D	D												
646615	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												
646527	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												
646647	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												
646675	E	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	D			

INDIVIDUAL ANIMAL ESTROUS CYCLE STAGES DURING PREMATING AND COHABITATION

GROUP VIII-0: 500 MG/KG/DAY

ANIMAL NUMBER	TEST DAYS																																			
	52	53	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	
646662	D	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646583	D	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646623	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646619	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646539	E	D	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646628	D	E	E	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646616	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646563	D	D	E	E	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646641	D	D	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646572	E	D	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646512	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646566	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646570	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646602	D	D	E	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646582	D	D	E	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646655	D	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646663	E	D	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646640	D	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646574C	E	E	D	D	D	D	E	D	D	D	D	E	D	D	D	D	D	D	D	D	D	D														
646532C	E	E	D	D	D	D	E	D	D	D	D	E	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
646490	95	646356	97
646378	100	646491	92
646353	94	646402	89
646382	93	646334	90
646440	98	646330	94
646483	96	646351	89
646341	97	646392	97
646406	94	646493	95
646424	97	646499	95
646363	93	646405	92

GROUP V-0 100 MG/KG/DAY		GROUP VII-0 500 MG/KG/DAY	
Animal Number	Percent Motile	Animal Number	Percent Motile
646473	87	646338	86
646404	86	646497	95
646400	97	646357	95
646418	95	646340	83
646395	97	646394	89
646415	94	646401	84
646417	95	646409	92
646362	92	646354	91
646352	81	646387	90
646410	89	646498	85

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
646490	196	2	2	0	98.0
646440	195	1	4	0	97.5
646424	197	0	3	0	98.5
646402	199	1	0	0	99.5
646392	197	0	3	0	98.5
646473	196	2	2	0	98.0
646395	197	0	3	0	98.5
646352	196	1	3	0	98.0
646357	197	3	0	0	98.5
646409	196	0	4	0	98.0

GROUP III-0: 25 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
646378	200	0	0	0	100.0
646483	200	0	0	0	100.0
646363	197	0	3	0	98.5
646334	193	7	0	0	96.5
646493	198	0	2	0	99.0
646404	196	1	3	0	98.0
646415	196	0	4	0	98.0
646410	199	0	1	0	99.5
646340	191	1	8	0	95.5
646354	195	0	5	0	97.5

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
646353	197	0	3	0	98.5
646341	198	1	1	0	99.0
646356	198	1	1	0	99.0
646330	196	1	3	0	98.0
646499	199	1	0	0	99.5
646400	196	1	3	0	98.0
646417	200	0	0	0	100.0
646338	198	0	2	0	99.0
646394	197	0	3	0	98.5
646387	198	1	1	0	99.0

GROUP VII-0: 500 MG/KG/DAY

Animal Number	Total Normal	Tail Abnormal	Head Abnormal	Tail & Head Abnormal	Percent Normal
646382	193	2	5	0	96.5
646406	199	0	1	0	99.5
646491	195	2	3	0	97.5
646351	197	0	3	0	98.5
646405	197	0	3	0	98.5
646418	195	1	4	0	97.5
646362	196	0	4	0	98.0
646497	185	0	15	0	92.5
646401	199	0	1	0	99.5
646498	198	0	2	0	99.0

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
646490	300.4	1324.1	149.1	91.5
646440	266.5	1170.5	115.2	82.6
646424	321.5	1074.1	129.8	86.7
646402	322.7	1181.0	121.0	85.4
646392	372.9	1263.3	122.2	81.4
646473	319.2	1228.4	132.7	85.2
646395	327.3	1064.8	124.5	80.0
646352	284.1	1132.2	126.9	83.9
646357	305.1	1078.5	119.8	76.2
646409	364.7	1285.2	123.4	79.9

GROUP III-0: 25 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
646378	292.3	1107.0	142.6	96.1
646483	288.8	836.0	140.3	78.9
646363	281.7	891.8	114.6	82.4
646334	295.8	893.3	132.1	89.0
646493	274.7	1037.1	131.5	87.0
646404	281.7	1012.7	131.5	118.6
646415	264.2	916.1	123.9	77.1
646410	295.8	1275.4	120.4	104.5
646340	238.5	986.7	125.1	94.8
646354	274.7	835.5	126.3	108.2

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
646353	265.4	781.4	145.0	93.6
646341	267.7	970.3	121.6	73.0
646356	280.6	1023.2	132.7	89.2
646330	277.1	1026.1	119.3	92.0
646499	320.3	941.8	125.1	86.0
646400	263.0	973.5	142.6	79.8
646417	340.2	1132.1	130.4	86.1
646338	309.8	1062.7	123.4	115.2
646394	268.9	879.2	113.4	78.3
646387	318.0	900.0	128.6	81.0

GROUP VII-0: 500 MG/KG/DAY

Animal Number	Epididymal Sperm		Testicular Spermatids	
	Per cauda	Per g cauda	Per testis	Per g testis
646382	258.4	1068.4	131.5	79.0
646406	277.1	1159.2	144.4	82.8
646491	258.4	835.3	146.7	95.2
646351	289.9	1223.3	149.1	85.6
646405	301.6	1136.8	129.8	80.8
646418	282.9	1039.7	146.7	85.6
646362	244.3	928.3	124.5	89.9
646497	316.8	1320.0	138.0	96.8
646401	275.9	882.3	138.5	74.3
646498	288.8	1027.6	121.0	63.7

APPENDIX DD

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

EXPLANATORY NOTES

Note

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

Footnote

- a* Because a copulatory plug was not observed, the start of gestation is unknown and, therefore, gestation length cannot be determined.
- b* Start of gestation miscalculated; gestation length unknown.
- c* No litter delivered, however, implantation sites were observed at necropsy.

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)
646653	646490	+			+	23
646575	646440	+			+	23
646585	646424	+			-	--
646622	646402	+			+	22
646550	646392	+			+	23
646526	646473	+			+	23
646503	646395	+			+	23
646644	646352	-			+	-- ^a
646604	646357	+			+	22
646651	646409	+			+	23
646552	646328	+			-	--
646606	646479	+			+	22
646557	646470	+			+	23
646591	646461	+			+	22
646544	646480	+			+	23
646646	646383	+			+	22
646520	646445	+			-	--
646569	646358	+			+	22
646654	646425	+			+	22
646668	646408	+			+	23

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)
646638	646378	+			+	22
646559	646483	+			+	23
646598	646363	+			-	--
646561	646334	+			+	23
646573	646493	+			-	--
646504	646404	+			+	22
646587	646415	+			-	--
646631	646410	+			-	--
646529	646340	+			+	22
646603	646354	+			+	22
646554	646467	+			-	--
646579	646381	+			+	22
646564	646342	+			-	--
646672	646450	+			+	23
646584	646326	+			-	--
646543	646377	+			+	23
646596	646478	+			+	22
646558	646350	+			-	--
646670	646333	+			-	--
646553	646486	+			+	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)
646547	646353	+			+	22
646666	646341	+			-	--
646607	646356	+			+	23
646524	646330	-			-	--
646600	646499	+			+	22
646648	646400	+			+	22
646594	646417	+			+	22
646546	646338	+			+	22
646661	646394	+			-	--
646671	646387	+			+	23
646521	646447	+			+	23
646590	646336	+			-	--
646645	646366	+			+	23
646555	646496	+			-	--
646605	646375	+			-	--
646589	646465	+			-	--
646615	646390	+			+	23
646527	646429	+			-	--
646647	646476	+			+	23
646675	646348	+			-	--

INDIVIDUAL MATING DATA AND GESTATION LENGTH: P₁ GENERATION

GROUPS: VIII-0,VII-0

DOSE: 500 MG/KG/DAY

FEMALE ANIMAL#	MALE #1 ANIMAL#	PLUG OBSERVED	MALE #2 ANIMAL#	PLUG OBSERVED	LITTER PRODUCED	GESTATION LENGTH(days)
646662	646382	+			+	23
646583	646406	+			-	--
646623	646491	+			+	23
646619	646351	+			+	23
646539	646405	+			+	23
646628	646418	+			-	--
646616	646362	+			-	--
646563	646497	+			-	--
646641	646401	+			+	23
646572	646498	+			+	23
646512	646386	+			+	22
646566	646332	+			+	23
646570	646441	+			-	--
646602	646452	+			+	23
646582	646365	+			-	--
646655	646393	+			+	23
646663	646359	+			+	16 ^b
646640	646451	+			-	-- ^c
646574	646491	+			+	23
646532	646351	+			+	23

APPENDIX EE
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

EXPLANATORY NOTES

Footnotes

- a* Number of pups born exceeded the number of implantation sites counted; implantation efficiency cannot be determined.
- b* Litter was counted before delivery was complete; number of pups born unknown. Implantation efficiency cannot be determined.
- c* No litter produced; therefore implantation efficiency cannot be determined.

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
646653	16	17	94.1
646575	9	12	75.0
646622	14	17	82.4
646550	15	18	83.3
646526	11	13	84.6
646503	16	11	---a
646644	14	15	93.3
646604	15	15	100.0
646651 ^b	---	16	---
646606	15	16	93.8
646557	12	12	100.0
646591	14	15	93.3
646544	13	14	92.9
646646	18	16	---a
646569	19	20	95.0
646654	13	14	92.9
646668	15	19	78.9

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
646638	18	18	100.0
646559	13	14	92.9
646561	7	7	100.0
646504	14	15	93.3
646529	12	14	85.7
646603	18	19	94.7
646579	15	16	93.8
646672	13	14	92.9
646543 ^b	---	8	---
646596	16	17	94.1
646553	11	13	84.6

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
646547	17	19	89.5
646607	14	16	87.5
646600	17	18	94.4
646648	8	10	80.0
646594	12	11	---a
646546	15	15	100.0
646671	14	18	77.8
646521	8	9	88.9
646645	14	16	87.5
646615	12	15	80.0
646647	16	16	100.0

INDIVIDUAL IMPLANTATION SITE DATA AND IMPLANTATION EFFICIENCY

GROUPS: VIII-0

DOSE: 500 MG/KG/DAY

Animal Number	Pups Born	Number of Implantation Sites	Implantation Efficiency
646662	11	13	84.6
646623	6	6	100.0
646619	13	13	100.0
646539	12	14	85.7
646641	13	15	86.7
646572	14	9	---a
646512	9	14	64.3
646566	10	10	100.0
646602	5	5	100.0
646655	12	16	75.0
646663	13	13	100.0
646640 ^c	---	1	---
646574	3	7	42.9
646532	13	14	92.9

APPENDIX FF
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered.
- b* Litter was counted before delivery was completed.
- c* No litter observed; however, implantation sites were present at necropsy.

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	BORN	NUMBER OF PUPS					
		BORN	PRECULLING	POSTCULLING	DAY 7	DAY 14	DAY 21
		ALIVE	DAY 4	DAY 4			
646653	16	16	14	8	8	8	8
646575	9	9	9	8	8	8	8
646585 ^a	---	---	---	---	---	---	---
646622	14	14	14	8	8	8	8
646550	15	15	15	8	8	8	8
646526	11	11	11	8	8	8	8
646503	16	16	13	8	8	8	8
646644	14	14	13	8	8	8	8
646604	15	15	15	8	8	8	8
646651	--- ^b	--- ^b	16	8	8	8	8
646552 ^a	---	---	---	---	---	---	---
646606	15	15	15	8	8	8	8
646557	12	12	12	8	8	8	8
646591	14	14	14	8	8	8	8
646544	13	13	13	8	8	8	8
646646	18	18	18	8	8	8	8
646520 ^a	---	---	---	---	---	---	---
646569	19	19	19	8	8	8	8
646654	13	13	13	8	8	8	8
646668	15	15	15	8	8	8	8

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: II-0

DOSE: 0 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF MALE PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646653	8	8	7	4	4	4	4
646575	3	3	3	3	3	3	3
646585 ^a	---	---	---	---	---	---	---
646622	6	6	6	4	4	4	4
646550	6	6	6	4	4	4	4
646526	8	8	8	5	5	5	5
646503	9	9	8	4	4	4	4
646644	1	1	1	1	1	1	1
646604	8	8	8	4	4	4	4
646651	--- ^b	--- ^b	6	4	4	4	4
646552 ^a	---	---	---	---	---	---	---
646606	4	4	4	4	4	4	4
646557	6	6	6	4	4	4	4
646591	10	10	10	4	4	4	4
646544	5	5	5	4	4	4	4
646646	10	10	10	4	4	4	4
646520 ^a	---	---	---	---	---	---	---
646569	12	12	12	4	4	4	4
646654	8	8	8	4	4	4	4
646668	8	8	8	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	BORN	NUMBER OF FEMALE PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646653	8	8	7	4	4	4	4
646575	6	6	6	5	5	5	5
646585 ^a	---	---	---	---	---	---	---
646622	8	8	8	4	4	4	4
646550	9	9	9	4	4	4	4
646526	3	3	3	3	3	3	3
646503	7	7	5	4	4	4	4
646644	13	13	12	7	7	7	7
646604	7	7	7	4	4	4	4
646651	--- ^b	--- ^b	10	4	4	4	4
646552 ^a	---	---	---	---	---	---	---
646606	11	11	11	4	4	4	4
646557	6	6	6	4	4	4	4
646591	4	4	4	4	4	4	4
646544	8	8	8	4	4	4	4
646646	8	8	8	4	4	4	4
646520 ^a	---	---	---	---	---	---	---
646569	7	7	7	4	4	4	4
646654	5	5	5	4	4	4	4
646668	7	7	7	4	4	4	4

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	NUMBER OF PUPS			LACTATION INDEX
	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	
646653	0.50	100.0	87.5	100.0
646575	0.33	100.0	100.0	100.0
646585 ^a	---	---	---	---
646622	0.43	100.0	100.0	100.0
646550	0.40	100.0	100.0	100.0
646526	0.73	100.0	100.0	100.0
646503	0.56	100.0	81.3	100.0
646644	0.07	100.0	92.9	100.0
646604	0.53	100.0	100.0	100.0
646651	--- ^b	--- ^b	--- ^b	100.0
646552 ^a	---	---	---	---
646606	0.27	100.0	100.0	100.0
646557	0.50	100.0	100.0	100.0
646591	0.71	100.0	100.0	100.0
646544	0.38	100.0	100.0	100.0
646646	0.56	100.0	100.0	100.0
646520 ^a	---	---	---	---
646569	0.63	100.0	100.0	100.0
646654	0.62	100.0	100.0	100.0
646668	0.53	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
646653	100.0	87.5	100.0
646575	100.0	100.0	100.0
646585 ^a	---	---	---
646622	100.0	100.0	100.0
646550	100.0	100.0	100.0
646526	100.0	100.0	100.0
646503	100.0	88.9	100.0
646644	100.0	100.0	100.0
646604	100.0	100.0	100.0
646651	--- ^b	--- ^b	100.0
646552 ^a	---	---	---
646606	100.0	100.0	100.0
646557	100.0	100.0	100.0
646591	100.0	100.0	100.0
646544	100.0	100.0	100.0
646646	100.0	100.0	100.0
646520 ^a	---	---	---
646569	100.0	100.0	100.0
646654	100.0	100.0	100.0
646668	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	NUMBER OF FEMALE PUPS		
	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
646653	100.0	87.5	100.0
646575	100.0	100.0	100.0
646585 ^a	---	---	---
646622	100.0	100.0	100.0
646550	100.0	100.0	100.0
646526	100.0	100.0	100.0
646503	100.0	71.4	100.0
646644	100.0	92.3	100.0
646604	100.0	100.0	100.0
646651	--- ^b	--- ^b	100.0
646552 ^a	---	---	---
646606	100.0	100.0	100.0
646557	100.0	100.0	100.0
646591	100.0	100.0	100.0
646544	100.0	100.0	100.0
646646	100.0	100.0	100.0
646520 ^a	---	---	---
646569	100.0	100.0	100.0
646654	100.0	100.0	100.0
646668	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		
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
646638	18	18	18	8	8	8	8
646559	13	13	11	8	8	8	8
646598 ^a	---	---	---	---	---	---	---
646561	7	7	7	7	7	7	7
646573 ^a	---	---	---	---	---	---	---
646504	14	14	14	8	8	8	8
646587 ^a	---	---	---	---	---	---	---
646631 ^a	---	---	---	---	---	---	---
646529	12	12	12	8	8	8	8
646603	18	18	18	8	8	8	8
646554 ^a	---	---	---	---	---	---	---
646579	15	15	15	8	8	8	8
646564 ^a	---	---	---	---	---	---	---
646672	13	13	13	8	8	8	8
646584 ^a	---	---	---	---	---	---	---
646543	--- ^b	--- ^b	8	8	8	8	8
646596	16	14	14	8	8	8	8
646558 ^a	---	---	---	---	---	---	---
646670 ^a	---	---	---	---	---	---	---
646553	11	11	11	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 ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646638	10	10	10	4	4	4	4
646559	6	6	6	4	4	4	4
646598 ^a	---	---	---	---	---	---	---
646561	6	6	6	6	6	6	6
646573 ^a	---	---	---	---	---	---	---
646504	11	11	11	5	5	5	5
646587 ^a	---	---	---	---	---	---	---
646631 ^a	---	---	---	---	---	---	---
646529	9	9	9	5	5	5	5
646603	11	11	11	4	4	4	4
646554 ^a	---	---	---	---	---	---	---
646579	9	9	9	4	4	4	4
646564 ^a	---	---	---	---	---	---	---
646672	5	5	5	4	4	4	4
646584 ^a	---	---	---	---	---	---	---
646543	--- ^b	--- ^b	3	3	3	3	3
646596	9	9	9	4	4	4	4
646558 ^a	---	---	---	---	---	---	---
646670 ^a	---	---	---	---	---	---	---
646553	2	2	2	2	2	2	2

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	BORN	NUMBER OF FEMALE PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646638	8	8	8	4	4	4	4
646559	7	7	5	4	4	4	4
646598 ^a	---	---	---	---	---	---	---
646561	1	1	1	1	1	1	1
646573 ^a	---	---	---	---	---	---	---
646504	3	3	3	3	3	3	3
646587 ^a	---	---	---	---	---	---	---
646631 ^a	---	---	---	---	---	---	---
646529	3	3	3	3	3	3	3
646603	7	7	7	4	4	4	4
646554 ^a	---	---	---	---	---	---	---
646579	6	6	6	4	4	4	4
646564 ^a	---	---	---	---	---	---	---
646672	8	8	8	4	4	4	4
646584 ^a	---	---	---	---	---	---	---
646543	--- ^b	--- ^b	5	5	5	5	5
646596	7	5	5	4	4	4	4
646558 ^a	---	---	---	---	---	---	---
646670 ^a	---	---	---	---	---	---	---
646553	9	9	9	6	6	6	6

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	NUMBER OF PUPS			LACTATION INDEX
	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	
646638	0.56	100.0	100.0	100.0
646559	0.46	100.0	84.6	100.0
646598 ^a	---	---	---	---
646561	0.86	100.0	100.0	100.0
646573 ^a	---	---	---	---
646504	0.79	100.0	100.0	100.0
646587 ^a	---	---	---	---
646631 ^a	---	---	---	---
646529	0.75	100.0	100.0	100.0
646603	0.61	100.0	100.0	100.0
646554 ^a	---	---	---	---
646579	0.60	100.0	100.0	80.0
646564 ^a	---	---	---	---
646672	0.38	100.0	100.0	100.0
646584 ^a	---	---	---	---
646543	--- ^b	--- ^b	--- ^b	100.0
646596	0.56	87.5	100.0	100.0
646558 ^a	---	---	---	---
646670 ^a	---	---	---	---
646553	0.18	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	% BORN ALIVE	NUMBER OF MALE PUPS	
		0-4 DAY VIABILITY	LACTATION INDEX
646638	100.0	100.0	100.0
646559	100.0	100.0	100.0
646598 ^a	---	---	---
646561	100.0	100.0	100.0
646573 ^a	---	---	---
646504	100.0	100.0	100.0
646587 ^a	---	---	---
646631 ^a	---	---	---
646529	100.0	100.0	100.0
646603	100.0	100.0	100.0
646554 ^a	---	---	---
646579	100.0	100.0	100.0
646564 ^a	---	---	---
646672	100.0	100.0	100.0
646584 ^a	---	---	---
646543	--- ^b	--- ^b	100.0
646596	100.0	100.0	100.0
646558 ^a	---	---	---
646670 ^a	---	---	---
646553	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: IV-0

DOSE: 25 MG/KG/DAY

ANIMAL NUMBER	% BORN ALIVE	NUMBER OF FEMALE PUPS	
		0-4 DAY VIABILITY	LACTATION INDEX
646638	100.0	100.0	100.0
646559	100.0	71.4	100.0
646598 ^a	---	---	---
646561	100.0	100.0	100.0
646573 ^a	---	---	---
646504	100.0	100.0	100.0
646587 ^a	---	---	---
646631 ^a	---	---	---
646529	100.0	100.0	100.0
646603	100.0	100.0	100.0
646554 ^a	---	---	---
646579	100.0	100.0	66.7
646564 ^a	---	---	---
646672	100.0	100.0	100.0
646584 ^a	---	---	---
646543	--- ^b	--- ^b	100.0
646596	71.4	100.0	100.0
646558 ^a	---	---	---
646670 ^a	---	---	---
646553	100.0	100.0	100.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	NUMBER OF PUPS						
	BORN	BORN ALIVE	PRECULLING		POSTCULLING		
			DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
646547	17	17	16	8	8	3	2
646666 ^a	---	---	---	---	---	---	---
646607	14	14	14	8	5	0	0
646524 ^a	---	---	---	---	---	---	---
646600	17	17	17	8	8	7	7
646648	8	8	8	8	8	8	8
646594	12	12	12	8	8	6	6
646546	15	15	15	8	8	8	8
646661 ^a	---	---	---	---	---	---	---
646671	14	13	13	8	8	6	5
646521	8	8	8	8	8	8	8
646590 ^a	---	---	---	---	---	---	---
646645	14	12	12	8	8	7	7
646555 ^a	---	---	---	---	---	---	---
646605 ^a	---	---	---	---	---	---	---
646589 ^a	---	---	---	---	---	---	---
646615	12	12	12	8	8	8	8
646527 ^a	---	---	---	---	---	---	---
646647	16	16	15	8	8	8	8
646675 ^a	---	---	---	---	---	---	---

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	BORN	NUMBER OF MALE PUPS					
		BORN	PRECULLING		POSTCULLING		
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
646547	4	4	4	4	4	2	2
646666 ^a	---	---	---	---	---	---	---
646607	8	8	8	4	3	0	0
646524 ^a	---	---	---	---	---	---	---
646600	9	9	9	4	4	4	4
646648	6	6	6	6	6	6	6
646594	8	8	8	4	4	4	4
646546	9	9	9	4	4	4	4
646661 ^a	---	---	---	---	---	---	---
646671	3	3	3	3	3	2	2
646521	2	2	2	2	2	2	2
646590 ^a	---	---	---	---	---	---	---
646645	7	6	6	4	4	3	3
646555 ^a	---	---	---	---	---	---	---
646605 ^a	---	---	---	---	---	---	---
646589 ^a	---	---	---	---	---	---	---
646615	4	4	4	4	4	4	4
646527 ^a	---	---	---	---	---	---	---
646647	13	13	13	6	6	6	6
646675 ^a	---	---	---	---	---	---	---

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
646547	13	13	12	4	4	1	0
646666 ^a	---	---	---	---	---	---	---
646607	6	6	6	4	2	0	0
646524 ^a	---	---	---	---	---	---	---
646600	8	8	8	4	4	3	3
646648	2	2	2	2	2	2	2
646594	4	4	4	4	4	2	2
646546	6	6	6	4	4	4	4
646661 ^a	---	---	---	---	---	---	---
646671	11	10	10	5	5	4	3
646521	6	6	6	6	6	6	6
646590 ^a	---	---	---	---	---	---	---
646645	7	6	6	4	4	4	4
646555 ^a	---	---	---	---	---	---	---
646605 ^a	---	---	---	---	---	---	---
646589 ^a	---	---	---	---	---	---	---
646615	8	8	8	4	4	4	4
646527 ^a	---	---	---	---	---	---	---
646647	3	3	2	2	2	2	2
646675 ^a	---	---	---	---	---	---	---

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

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

ANIMAL NUMBER	SEX RATIO (MALES)	NUMBER OF PUPS		LACTATION INDEX
		% BORN ALIVE	0-4 DAY VIABILITY	
646547	0.24	100.0	94.1	25.0
646666 ^a	---	---	---	---
646607	0.57	100.0	100.0	0.0
646524 ^a	---	---	---	---
646600	0.53	100.0	100.0	87.5
646648	0.75	100.0	100.0	100.0
646594	0.67	100.0	100.0	75.0
646546	0.60	100.0	100.0	100.0
646661 ^a	---	---	---	---
646671	0.21	92.9	100.0	62.5
646521	0.25	100.0	100.0	100.0
646590 ^a	---	---	---	---
646645	0.50	85.7	100.0	87.5
646555 ^a	---	---	---	---
646605 ^a	---	---	---	---
646589 ^a	---	---	---	---
646615	0.33	100.0	100.0	100.0
646527 ^a	---	---	---	---
646647	0.81	100.0	93.8	100.0
646675 ^a	---	---	---	---

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
646547	100.0	100.0	50.0
646666 ^a	---	---	---
646607	100.0	100.0	0.0
646524 ^a	---	---	---
646600	100.0	100.0	100.0
646648	100.0	100.0	100.0
646594	100.0	100.0	100.0
646546	100.0	100.0	100.0
646661 ^a	---	---	---
646671	100.0	100.0	66.7
646521	100.0	100.0	100.0
646590 ^a	---	---	---
646645	85.7	100.0	75.0
646555 ^a	---	---	---
646605 ^a	---	---	---
646589 ^a	---	---	---
646615	100.0	100.0	100.0
646527 ^a	---	---	---
646647	100.0	100.0	100.0
646675 ^a	---	---	---

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
646547	100.0	92.3	0.0
646666 ^a	---	---	---
646607	100.0	100.0	0.0
646524 ^a	---	---	---
646600	100.0	100.0	75.0
646648	100.0	100.0	100.0
646594	100.0	100.0	50.0
646546	100.0	100.0	100.0
646661 ^a	---	---	---
646671	90.9	100.0	60.0
646521	100.0	100.0	100.0
646590 ^a	---	---	---
646645	85.7	100.0	100.0
646555 ^a	---	---	---
646605 ^a	---	---	---
646589 ^a	---	---	---
646615	100.0	100.0	100.0
646527 ^a	---	---	---
646647	100.0	66.7	100.0
646675 ^a	---	---	---

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646662	11	11	11	8	6	0	0
646583 ^a	---	---	---	---	---	---	---
646623	6	6	5	5	1	0	0
646619	13	13	0	0	0	0	0
646539	12	12	8	8	4	0	0
646628 ^a	---	---	---	---	---	---	---
646616 ^a	---	---	---	---	---	---	---
646563 ^a	---	---	---	---	---	---	---
646641	13	11	11	8	7	0	0
646572	14	13	8	8	5	0	0
646512	9	9	9	8	7	0	0
646566	10	9	9	8	8	4	3
646570 ^a	---	---	---	---	---	---	---
646602	5	5	5	5	5	0	0
646582 ^a	---	---	---	---	---	---	---
646655	12	10	10	8	4	0	0
646663	13	10	9	8	8	6	5
646640 ^c	---	---	---	---	---	---	---
646574	3	0	0	0	0	0	0
646532	13	13	12	8	8	4	2

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF MALE PUPS					
		BORN	PRECULLING	POSTCULLING			
		ALIVE	DAY 4	DAY 4	DAY 7	DAY 14	DAY 21
646662	4	4	4	4	4	0	0
646583 ^a	---	---	---	---	---	---	---
646623	3	3	2	2	0	0	0
646619	5	5	0	0	0	0	0
646539	4	4	4	4	1	0	0
646628 ^a	---	---	---	---	---	---	---
646616 ^a	---	---	---	---	---	---	---
646563 ^a	---	---	---	---	---	---	---
646641	5	4	4	4	3	0	0
646572	7	6	4	4	2	0	0
646512	6	6	6	5	5	0	0
646566	6	5	5	4	4	2	1
646570 ^a	---	---	---	---	---	---	---
646602	3	3	3	3	3	0	0
646582 ^a	---	---	---	---	---	---	---
646655	7	6	6	4	2	0	0
646663	6	5	4	4	4	4	3
646640 ^a	---	---	---	---	---	---	---
646574	0	0	0	0	0	0	0
646532	8	8	8	4	4	1	1

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	BORN	NUMBER OF FEMALE PUPS					
		BORN ALIVE	PRECULLING DAY 4	POSTCULLING DAY 4	DAY 7	DAY 14	DAY 21
646662	7	7	7	4	2	0	0
646583 ^a	---	---	---	---	---	---	---
646623	3	3	3	3	1	0	0
646619	8	8	0	0	0	0	0
646539	8	8	4	4	3	0	0
646628 ^a	---	---	---	---	---	---	---
646616 ^a	---	---	---	---	---	---	---
646563 ^a	---	---	---	---	---	---	---
646641	8	7	7	4	4	0	0
646572	7	7	4	4	3	0	0
646512	3	3	3	3	2	0	0
646566	4	4	4	4	4	2	2
646570 ^a	---	---	---	---	---	---	---
646602	2	2	2	2	2	0	0
646582 ^a	---	---	---	---	---	---	---
646655	5	4	4	4	2	0	0
646663	6	5	5	4	4	2	2
646640 ^a	---	---	---	---	---	---	---
646574	3	0	0	0	0	0	0
646532	5	5	4	4	4	3	1

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	NUMBER OF PUPS			LACTATION INDEX
	SEX RATIO (MALES)	% BORN ALIVE	0-4 DAY VIABILITY	
646662	0.36	100.0	100.0	0.0
646583 ^a	---	---	---	---
646623	0.50	100.0	83.3	0.0
646619	0.38	100.0	0.0	---
646539	0.33	100.0	66.7	0.0
646628 ^a	---	---	---	---
646616 ^a	---	---	---	---
646563 ^a	---	---	---	---
646641	0.38	84.6	100.0	0.0
646572	0.50	92.9	61.5	0.0
646512	0.67	100.0	100.0	0.0
646566	0.60	90.0	100.0	37.5
646570 ^a	---	---	---	---
646602	0.60	100.0	100.0	0.0
646582 ^a	---	---	---	---
646655	0.58	83.3	100.0	0.0
646663	0.50	76.9	90.0	62.5
646640 ^a	---	---	---	---
646574	0.00	0.0	---	---
646532	0.62	100.0	92.3	25.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	% BORN ALIVE	NUMBER OF MALE PUPS		LACTATION INDEX
		0-4 DAY VIABILITY		
646662	100.0	100.0		0.0
646583 ^a	---	---		---
646623	100.0	66.7		0.0
646619	100.0	0.0		---
646539	100.0	100.0		0.0
646628 ^a	---	---		---
646616 ^a	---	---		---
646563 ^a	---	---		---
646641	80.0	100.0		0.0
646572	85.7	66.7		0.0
646512	100.0	100.0		0.0
646566	83.3	100.0		25.0
646570 ^a	---	---		---
646602	100.0	100.0		0.0
646582 ^a	---	---		---
646655	85.7	100.0		0.0
646663	83.3	80.0		75.0
646640 ^a	---	---		---
646574	---	---		---
646532	100.0	100.0		25.0

INDIVIDUAL PUP SURVIVAL: F₁ GENERATION

GROUP: VIII-0 DOSE: 500 MG/KG/DAY

NUMBER OF FEMALE PUPS			
ANIMAL NUMBER	% BORN ALIVE	0-4 DAY VIABILITY	LACTATION INDEX
646662	100.0	100.0	0.0
646583 ^a	---	---	---
646623	100.0	100.0	0.0
646619	100.0	0.0	---
646539	100.0	50.0	0.0
646628 ^a	---	---	---
646616 ^a	---	---	---
646563 ^a	---	---	---
646641	87.5	100.0	0.0
646572	100.0	57.1	0.0
646512	100.0	100.0	0.0
646566	100.0	100.0	50.0
646570 ^a	---	---	---
646602	100.0	100.0	0.0
646582 ^a	---	---	---
646655	80.0	100.0	0.0
646663	83.3	100.0	50.0
646640 ^a	---	---	---
646574	0.0	---	---
646532	100.0	80.0	25.0

APPENDIX GG
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL PUP WEIGHTS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL PUP WEIGHTS: F₁ GENERATION

EXPLANATORY NOTES

Footnotes

- a* No litter delivered.
- b* Litter was weighed before delivery was complete.
- c* One pup was missexed; data were excluded from male and female mean pup weights.
- d* No litter observed; however, implantation sites were observed at necropsy.
- e* No live pups.
- f* No live male pups.
- g* No live female pups.

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

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	13
646653	♂	7.80	7.30	7.60	6.20	7.60	7.60	7.60	7.60					
	♀	7.30	7.80	6.90	7.10	7.50	7.20	6.00	6.50					
646575	♂	7.90	8.10	7.90										
	♀	7.20	7.50	7.30	7.70	7.30	6.70							
646585 ^a	♂													
	♀													
646622	♂	6.70	6.30	6.70	6.50	6.20	6.60							
	♀	6.70	6.50	6.50	6.70	6.20	6.60	6.40	5.70					
646550	♂	6.60	6.80	7.10	6.70	6.60	6.20							
	♀	6.60	6.40	6.00	5.90	5.90	6.00	6.60	6.30	6.60				
646526	♂	8.20	8.40	8.20	7.80	8.20	8.00	7.30	9.20					
	♀	8.10	7.80	8.10										
646503	♂	7.90	7.30	7.90	8.30	8.20	7.60	8.10	7.00	7.70				
	♀	8.10	7.50	7.50	6.50	7.20	7.20	8.20						
646644	♂	7.60												
	♀	6.30	7.00	7.30	6.80	6.60	6.70	6.60	4.50	6.90	6.60	6.50	7.00	6.30
646604	♂	6.50	6.70	6.60	6.40	6.50	6.10	6.30	6.90					
	♀	6.20	6.70	6.40	6.30	4.20	6.60	5.80						
646651 ^b	♂	8.50	7.50	7.70	7.20	6.20	8.00							
	♀	7.10	7.20	7.90	7.70	7.20	6.60							
646552 ^a	♂													
	♀													
646606	♂	6.40	6.40	6.90	6.70									
	♀	6.60	6.10	6.40	6.30	6.10	6.40	6.40	6.40	6.20	6.20	6.10		
646557	♂	8.20	8.00	7.60	8.50	7.80	8.40							
	♀	7.70	7.70	7.60	6.90	7.40	7.60							
646591	♂	7.10	6.70	7.40	7.10	7.50	6.90	7.20	7.00	7.30	7.10			
	♀	6.50	6.70	6.90	6.90									
646544	♂	7.60	7.30	7.40	8.10	8.70								
	♀	6.90	7.90	7.70	8.10	7.10	7.20	7.40	7.70					
646646	♂	6.50	6.50	5.80	5.90	5.90	6.40	5.90	5.50	5.80	5.80			
	♀	5.50	5.70	5.70	5.70	5.30	5.70	5.00	5.00					
646520 ^a	♂													
	♀													
646569	♂	5.40	5.50	6.10	5.70	6.00	5.60	4.70	5.50	4.10	6.20	5.90	5.60	
	♀	5.50	5.20	5.30	5.70	5.50	5.30	5.30						
646654	♂	7.50	6.70	7.20	6.90	6.70	6.90	7.30	7.30					
	♀	6.60	6.40	6.50	6.20	6.70								
646668	♂	7.80	7.40	7.70	7.50	7.20	7.50	7.70	7.40					
	♀	7.10	7.60	7.40	6.70	7.10	7.20	7.10						

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	12	13
646638	♂	7.10	6.90	6.70	6.70	6.80	6.80	6.40	6.30	6.30	6.60			
	♀	6.40	6.10	6.10	6.70	5.20	6.10	6.30	6.30					
646559	♂	8.10	6.90	7.30	7.90	7.80	7.90							
	♀	6.80	7.10	7.20	7.10	7.30	7.30	7.00						
646598 ^a	♂													
	♀													
646561	♂	8.60	8.80	8.10	8.30	8.30	8.40							
	♀	8.10												
646573 ^a	♂													
	♀													
646504 ^c	♂	6.60	6.00	6.60	6.40	6.40	6.30	6.50	5.80	6.30	6.40			
	♀	6.10	5.90	5.90	6.50									
646587 ^a	♂													
	♀													
646631 ^a	♂													
	♀													
646529	♂	6.50	6.80	6.40	6.80	6.20	6.30	6.20	6.60	6.60				
	♀	5.70	6.00	6.20										
646603	♂	5.70	6.40	6.20	6.90	5.70	5.90	6.20	6.00	6.10	5.90	6.00		
	♀	6.00	5.90	6.10	5.90	5.70	6.40	5.70						
646554 ^a	♂													
	♀													
646579	♂	5.20	6.60	6.00	6.50	6.30	6.40	6.30	6.50	6.20				
	♀	6.40	5.80	5.80	5.70	5.60	6.70							
646564 ^a	♂													
	♀													
646672	♂	8.40	8.40	8.50	8.90	8.90								
	♀	7.70	8.40	6.20	8.30	7.10	8.40	8.60	7.80					
646584 ^a	♂													
	♀													
646543 ^b	♂	7.70	7.80											
	♀	7.20	6.00	7.30	7.00	7.70								
646596	♂	5.60	5.90	6.60	5.50	6.40	6.30	6.00	6.40	6.80				
	♀	6.20	5.90	5.90	5.00	4.60								
646558 ^a	♂													
	♀													
646670 ^a	♂													
	♀													
646553	♂	7.30	7.30											
	♀	6.10	6.20	6.00	6.40	6.20	6.40	6.60	6.30	6.90				

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

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
646547	♂	6.40	6.90	6.30	6.60									
	♀	6.20	6.60	5.90	6.20	6.40	6.70	6.20	6.10	6.40	6.70	6.20	6.40	6.20
646666a	♂													
	♀													
646607	♂	7.60	7.20	7.40	7.70	6.60	7.30	6.50	7.30					
	♀	7.10	6.50	6.90	6.40	7.00	6.40							
646524a	♂													
	♀													
646600	♂	6.60	6.40	6.50	6.10	5.90	6.20	6.20	6.80	6.20				
	♀	6.00	5.70	6.00	6.10	6.70	6.20	6.30	6.50					
646648	♂	7.10	7.00	6.00	7.10	6.90	7.20							
	♀	6.90	6.70											
646594	♂	6.60	6.70	5.90	6.80	6.00	6.60	6.30	7.10					
	♀	6.10	6.60	6.00	5.90									
646546	♂	6.10	6.50	6.00	6.40	6.10	6.20	6.10	5.70	6.20				
	♀	6.00	5.40	5.60	6.20	6.30	6.50							
646661a	♂													
	♀													
646671	♂	6.50	7.20	6.90										
	♀	6.80	6.60	6.10	6.00	6.50	6.10	6.70	7.00	6.90	6.30			
646521	♂	7.90	8.30											
	♀	7.90	7.30	7.50	7.80	7.50	5.60							
646590a	♂													
	♀													
646645	♂	6.70	6.50	6.40	7.10	6.40	6.30							
	♀	6.40	5.80	6.80	6.20	6.40	4.40							
646555a	♂													
	♀													
646605a	♂													
	♀													
646589a	♂													
	♀													
646615	♂	8.20	7.70	7.20	7.90									
	♀	7.60	7.10	7.20	7.20	7.20	6.80	7.40	7.90					
646527a	♂													
	♀													
646647	♂	7.30	6.80	7.00	7.30	7.00	6.80	6.90	7.50	6.30	7.00	7.10	6.40	7.20
	♀	6.90	6.50	6.80										
646675a	♂													
	♀													

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

Group: VIII-0

Dose: 500 mg/kg/day

Animal Number	Pup Sex	Pup Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
646662	♂	6.60	6.40	6.70	5.80									
	♀	6.10	5.80	5.90	6.00	5.80	6.20	5.30						
646583 ^a	♂													
	♀													
646623	♂	7.20	6.90	6.90										
	♀	5.70	6.60	6.40										
646619	♂	6.20	7.00	6.50	7.00	7.20								
	♀	6.80	7.00	6.10	6.50	6.30	5.70	6.00	5.80					
646539	♂	6.60	6.30	6.50	6.60									
	♀	5.40	6.20	6.00	6.50	6.10	5.30	5.30	5.90					
646628 ^a	♂													
	♀													
646616 ^a	♂													
	♀													
646563 ^a	♂													
	♀													
646641	♂	6.90	6.80	6.70	6.00									
	♀	6.00	6.30	6.60	5.80	6.40	6.20	6.30						
646572	♂	5.80	6.10	5.60	6.00	5.40	5.80							
	♀	5.30	4.90	5.50	4.90	5.00	5.30	5.70						
646512	♂	6.30	5.70	6.40	6.50	6.00	6.70							
	♀	6.20	5.00	6.40										
646566	♂	6.60	6.50	7.10	6.40	6.70								
	♀	6.50	6.20	6.50	6.50									
646570 ^a	♂													
	♀													
646602 ^c	♂	7.50	7.40											
	♀	6.80	5.90	6.20										
646582 ^a	♂													
	♀													
646655	♂	6.40	6.20	6.80	5.90	6.00	6.50							
	♀	5.80	6.30	6.20	5.80									
646663	♂	5.40	5.60	5.90	5.30	5.40								
	♀	5.70	5.20	5.90	5.70	5.30								
646640 ^d	♂													
	♀													
646574 ^e	♂													
	♀													
646532	♂	7.40	6.50	6.50	7.00	6.70	6.60	7.20	6.70					
	♀	6.10	6.30	6.40	6.50	6.20								

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	13
646653	♂	11.8	11.4	11.8	12.7	11.8	10.5	13.3						
	♀	10.8	10.8	10.0	12.0	11.3	11.9	10.6						
646575	♂	14.5	13.1	14.2										
	♀	13.9	12.7	13.0	13.2	14.2	13.3							
646585 ^a	♂													
	♀													
646622	♂	10.0	10.7	10.6	11.3	10.6	10.0							
	♀	10.5	10.7	10.9	10.5	11.2	10.2	10.2	11.1					
646550	♂	7.90	7.50	7.60	7.00	7.60	6.90							
	♀	7.20	7.60	7.30	7.40	6.60	6.70	6.80	7.40	7.30				
646526	♂	15.5	16.5	15.3	15.0	15.1	15.4	14.8	13.6					
	♀	14.9	15.1	14.7										
646503	♂	11.7	13.3	14.3	13.1	14.2	14.1	13.4	14.3					
	♀	14.0	12.7	11.5	13.4	12.4								
646644	♂	12.6												
	♀	11.5	12.4	11.4	11.4	11.8	10.9	10.8	7.90	10.4	11.1	13.1	10.9	
646604	♂	9.60	11.0	9.40	10.2	10.4	11.3	11.2	10.6					
	♀	10.7	9.80	9.00	10.4	9.50	10.2	6.50						
646651	♂	11.3	10.9	11.3	13.2	11.9	11.7							
	♀	11.1	11.6	11.5	11.7	10.4	11.7	11.7	10.6	12.2	12.1			
646552 ^a	♂													
	♀													
646606	♂	11.8	11.7	11.1	11.3									
	♀	10.7	13.2	11.1	11.0	10.8	10.6	10.5	11.1	10.2	10.7	10.3		
646557	♂	12.4	13.0	12.8	13.0	13.0	11.5							
	♀	12.3	11.7	12.6	11.7	11.6	12.3							
646591	♂	12.4	12.1	13.2	11.8	11.5	11.8	11.0	11.8	11.7	11.2			
	♀	10.9	12.4	11.0	11.6									
646544	♂	14.6	13.8	13.6	15.5	14.9								
	♀	13.5	13.0	12.4	13.8	13.8	10.8	12.9	14.3					
646646	♂	9.80	8.80	9.60	8.80	11.0	7.10	9.90	10.9	10.0	11.1			
	♀	8.60	10.4	10.1	9.00	8.60	9.90	8.90	10.7					
646520 ^a	♂													
	♀													
646569	♂	9.30	9.00	10.5	8.30	9.70	7.00	7.70	6.90	8.80	10.9	9.00	9.10	
	♀	9.20	9.20	8.20	8.50	7.80	9.30	8.10						
646654	♂	13.8	13.0	11.8	12.1	13.2	12.7	12.6	13.5					
	♀	11.8	12.1	12.0	12.0	11.6								
646668	♂	11.6	12.6	11.8	12.9	11.4	13.0	12.4	13.4					
	♀	11.8	12.2	12.0	10.3	10.5	11.4	11.2						

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

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	12	13
646638	♂	11.1	10.6	10.7	9.20	11.3	10.4	12.0	11.7	11.4	10.8			
	♀	10.2	10.8	9.80	11.4	8.60	9.60	9.80	9.60					
646559	♂	13.4	13.0	12.4	11.2	12.2	13.7							
	♀	12.2	13.8	11.2	12.0	12.3								
646598 ^a	♂													
	♀													
646561	♂	16.2	17.1	16.1	16.4	16.5	16.5							
	♀	15.2												
646573 ^a	♂													
	♀													
646504	♂	11.3	11.0	10.9	10.7	10.8	10.0	11.2	11.1	10.8	11.5	10.9		
	♀	10.5	10.5	10.7										
646587 ^a	♂													
	♀													
646631 ^a	♂													
	♀													
646529	♂	12.1	13.5	12.6	12.9	12.4	13.7	13.2	12.9	12.3				
	♀	12.4	11.7	12.3										
646603	♂	10.0	10.6	11.8	10.1	10.6	9.90	10.7	10.6	11.5	10.5	10.4		
	♀	9.90	9.60	9.50	11.1	10.4	7.90	10.3						
646554 ^a	♂													
	♀													
646579	♂	9.90	9.60	10.2	10.6	10.2	8.20	10.5	10.6	10.0				
	♀	9.40	9.40	9.60	10.2	9.40	10.5							
646564 ^a	♂													
	♀													
646672	♂	14.1	14.9	15.5	15.5	15.4								
	♀	15.1	15.5	13.2	12.9	14.1	14.0	15.4	15.5					
646584 ^a	♂													
	♀													
646543	♂	14.0	15.1	14.0										
	♀	15.0	14.2	14.0	13.8	12.0								
646596	♂	10.0	11.3	9.50	11.3	12.1	9.50	11.3	11.7	11.6				
	♀	11.0	5.60	10.8	10.8	10.3								
646558 ^a	♂													
	♀													
646670 ^a	♂													
	♀													
646553	♂	13.2	13.3											
	♀	11.8	12.2	10.9	11.8	12.2	11.9	11.2	11.7	12.4				

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

Group: VI-0

Dose: 100 mg/kg/day

Animal Number	Pup Sex	Pup Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
646547	♂	10.7	7.10	8.60	10.0									
	♀	8.20	9.40	8.00	9.50	11.0	9.50	9.60	8.00	9.50	10.5	11.0	10.4	
646666 ^a	♂													
	♀													
646607	♂	8.20	7.30	8.90	7.10	10.0	9.00	8.60	8.70					
	♀	10.9	10.2	8.60	8.60	9.10	7.90							
646524 ^a	♂													
	♀													
646600	♂	10.3	10.1	9.90	10.9	11.6	7.60	11.4	12.4	11.7				
	♀	9.30	10.8	11.6	10.0	8.10	11.3	10.6	11.4					
646648	♂	14.0	14.9	12.5	13.1	13.0	13.4							
	♀	12.4	13.0											
646594	♂	11.0	13.0	12.9	12.8	12.3	12.7	11.6	10.4					
	♀	10.8	11.2	11.5	9.60									
646546	♂	10.8	10.9	11.2	11.0	10.6	8.90	10.3	9.00	11.0				
	♀	10.3	10.3	10.2	11.4	11.1	8.70							
646661 ^a	♂													
	♀													
646671	♂	8.40	9.90	10.2										
	♀	8.40	9.20	9.00	9.60	8.00	8.70	8.80	8.80	8.80	10.0			
646521	♂	12.4	12.9											
	♀	12.1	11.3	12.7	7.80	11.2	12.2							
646590 ^a	♂													
	♀													
646645	♂	12.6	12.2	13.3	13.0	10.3	12.4							
	♀	11.2	11.4	12.1	11.9	7.50	11.6							
646555 ^a	♂													
	♀													
646605 ^a	♂													
	♀													
646589 ^a	♂													
	♀													
646615	♂	12.9	12.9	13.1	11.4									
	♀	12.0	12.4	12.4	12.8	13.0	11.9	12.5	12.0					
646527 ^a	♂													
	♀													
646647	♂	10.9	8.60	9.90	10.0	9.00	10.3	9.00	10.8	10.6	10.0	10.7	9.90	9.10
	♀	9.30	8.30											
646675 ^a	♂													
	♀													

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

Group: VIII-0

Dose: 500 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>												
		1	2	3	4	5	6	7	8	9	10	11	12	13
646662	♂	7.40	8.50	7.20	8.30									
	♀	7.60	6.80	6.80	6.90	6.40	7.80	7.50						
646583 ^a	♂													
	♀													
646623	♂	8.30	7.40											
	♀	7.50	7.10	6.00										
646619 ^e	♂													
	♀													
646539	♂	6.40	6.30	6.70	6.70									
	♀	6.90	6.30	6.30	5.80									
646628 ^a	♂													
	♀													
646616 ^a	♂													
	♀													
646563 ^a	♂													
	♀													
646641	♂	8.40	7.00	9.10	7.80									
	♀	7.90	6.40	7.80	8.80	8.30	8.40	8.00						
646572	♂	6.00	5.20	6.00	6.50									
	♀	5.60	6.10	4.30	5.40									
646512	♂	9.40	8.60	9.60	10.5	8.40	8.80							
	♀	9.30	9.20	7.50										
646566	♂	12.1	9.50	10.5	7.60	8.80								
	♀	11.2	9.60	11.7	9.50									
646570 ^a	♂													
	♀													
646602	♂	10.1	11.4	11.9										
	♀	9.10	9.60											
646582 ^a	♂													
	♀													
646655	♂	8.40	8.70	9.10	8.00	9.00	8.90							
	♀	8.80	8.30	9.50	9.70									
646663	♂	8.30	7.70	6.50	7.80									
	♀	9.60	8.30	8.80	6.30	6.10								
646640 ^d	♂													
	♀													
646574 ^e	♂													
	♀													
646532	♂	10.1	9.70	10.6	8.60	10.8	10.4	8.90	8.50					
	♀	9.90	9.40	10.2	7.00									

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	6	7
646653	♂	11.8	11.4	11.8	11.8			
	♀	11.3	12.0	11.9	10.6			
646575	♂	14.5	13.1	14.2				
	♀	13.9	12.7	13.0	13.2	14.2		
646585 ^a	♂							
	♀							
646622	♂	10.6	11.3	10.6	10.0			
	♀	10.9	11.2	10.2	11.1			
646550	♂	7.50	7.60	7.60	6.90			
	♀	7.60	7.30	6.70	7.40			
646526	♂	15.5	15.0	15.1	15.4	14.8		
	♀	14.9	15.1	14.7				
646503	♂	13.1	14.1	13.4	14.3			
	♀	12.7	11.5	13.4	12.4			
646644	♂	12.6						
	♀	12.4	11.4	11.4	11.8	10.9	10.4	11.1
646604	♂	9.40	10.2	11.2	10.6			
	♀	10.7	10.4	9.50	6.50			
646651	♂	10.9	11.3	11.9	11.7			
	♀	11.6	11.7	12.2	12.1			
646552 ^a	♂							
	♀							
646606	♂	11.8	11.7	11.1	11.3			
	♀	13.2	11.1	10.5	11.1			
646557	♂	13.0	12.8	13.0	11.5			
	♀	11.7	12.6	11.7	11.6			
646591	♂	11.8	11.5	11.8	11.2			
	♀	10.9	12.4	11.0	11.6			
646544	♂	14.6	13.6	15.5	14.9			
	♀	13.0	13.8	12.9	14.3			
646646	♂	11.0	7.10	10.9	10.0			
	♀	10.1	9.00	9.90	8.90			
646520 ^a	♂							
	♀							
646569	♂	9.00	10.5	8.80	9.00			
	♀	9.20	8.50	9.30	8.10			
646654	♂	11.8	12.1	13.2	12.7			
	♀	12.1	12.0	12.0	11.6			
646668	♂	11.6	11.8	12.9	12.4			
	♀	12.2	12.0	10.3	10.5			

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

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646638	♂	11.3	10.4	12.0	11.4			
	♀	10.8	9.80	11.4	9.60			
646559	♂	13.0	12.4	11.2	13.7			
	♀	12.2	13.8	12.0	12.3			
646598 ^a	♂							
	♀							
646561	♂	16.2	17.1	16.1	16.4	16.5	16.5	
	♀	15.2						
646573 ^a	♂							
	♀							
646504	♂	11.3	11.0	10.9	10.7	11.1		
	♀	10.5	10.5	10.7				
646587 ^a	♂							
	♀							
646631 ^a	♂							
	♀							
646529	♂	12.9	12.4	13.7	13.2	12.9		
	♀	12.4	11.7	12.3				
646603	♂	10.6	11.8	10.6	9.90			
	♀	9.50	11.1	10.4	7.90			
646554 ^a	♂							
	♀							
646579	♂	10.6	10.2	8.20	10.5			
	♀	9.40	9.40	9.60	9.40			
646564 ^a	♂							
	♀							
646672	♂	14.1	15.5	15.5	15.4			
	♀	15.1	15.5	14.0	15.4			
646584 ^a	♂							
	♀							
646543	♂	14.0	15.1	14.0				
	♀	15.0	14.2	14.0	13.8	12.0		
646596	♂	11.3	11.3	9.50	11.6			
	♀	11.0	10.8	10.8	10.3			
646558 ^a	♂							
	♀							
646670 ^a	♂							
	♀							
646553	♂	13.2	13.3					
	♀	11.8	10.9	12.2	11.9	11.2	11.7	

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	6	7
646547	♂	10.7	7.10	8.60	10.0			
	♀	9.40	9.60	8.00	9.50			
646666a	♂							
	♀							
646607	♂	8.90	7.10	10.0	8.60			
	♀	10.9	10.2	8.60	9.10			
646524a	♂							
	♀							
646600	♂	10.1	9.90	11.6	11.4			
	♀	11.6	10.0	8.10	10.6			
646648	♂	14.0	14.9	12.5	13.1	13.0	13.4	
	♀	12.4	13.0					
646594	♂	13.0	12.3	12.7	10.4			
	♀	10.8	11.2	11.5	9.60			
646546	♂	10.8	10.9	11.2	10.6			
	♀	10.3	10.2	11.4	11.1			
646661a	♂							
	♀							
646671	♂	8.40	9.90	10.2				
	♀	9.60	8.70	8.80	8.80	10.0		
646521	♂	12.4	12.9					
	♀	12.1	11.3	12.7	7.80	11.2	12.2	
646590a	♂							
	♀							
646645	♂	12.6	12.2	13.3	10.3			
	♀	11.4	11.9	7.50	11.6			
646555a	♂							
	♀							
646605a	♂							
	♀							
646589a	♂							
	♀							
646615	♂	12.9	12.9	13.1	11.4			
	♀	12.4	12.8	13.0	11.9			
646527a	♂							
	♀							
646647	♂	9.90	10.8	10.6	10.0	9.90	9.10	
	♀	9.30	8.30					
646675a	♂							
	♀							

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

Group: VIII-0 Dose: 500 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646662	♂	7.40	8.50	7.20	8.30			
	♀	7.60	6.80	6.80	7.80			
646583 ^a	♂							
	♀							
646623	♂	8.30	7.40					
	♀	7.50	7.10	6.00				
646619 ^e	♂							
	♀							
646539	♂	6.40	6.30	6.70	6.70			
	♀	6.90	6.30	6.30	5.80			
646628 ^a	♂							
	♀							
646616 ^a	♂							
	♀							
646563 ^a	♂							
	♀							
646641	♂	8.40	7.00	9.10	7.80			
	♀	7.90	6.40	8.30	8.00			
646572	♂	6.00	5.20	6.00	6.50			
	♀	5.60	6.10	4.30	5.40			
646512	♂	8.60	9.60	10.5	8.40	8.80		
	♀	9.30	9.20	7.50				
646566	♂	12.1	9.50	10.5	8.80			
	♀	11.2	9.60	11.7	9.50			
646570 ^a	♂							
	♀							
646602	♂	10.1	11.4	11.9				
	♀	9.10	9.60					
646582 ^a	♂							
	♀							
646655	♂	8.40	9.10	9.00	8.90			
	♀	8.80	8.30	9.50	9.70			
646663	♂	8.30	7.70	6.50	7.80			
	♀	8.30	8.80	6.30	6.10			
646640 ^d	♂							
	♀							
646574 ^e	♂							
	♀							
646532	♂	9.70	10.6	10.8	8.90			
	♀	9.90	9.40	10.2	7.00			

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	6	7
646653	♂	19.0	20.0	18.7	19.5			
	♀	18.1	17.0	19.0	19.6			
646575	♂	20.3	18.4	20.2				
	♀	19.2	19.9	19.9	18.1	18.6		
646585a	♂							
	♀							
646622	♂	19.6	17.8	18.9	16.8			
	♀	17.5	16.8	17.5	17.6			
646550	♂	12.3	11.9	11.9	11.1			
	♀	10.9	11.7	10.8	11.1			
646526	♂	23.2	23.8	22.9	23.5	23.1		
	♀	22.7	22.7	22.4				
646503	♂	22.2	23.3	21.2	22.2			
	♀	21.4	19.8	18.9	21.3			
646644	♂	19.3						
	♀	17.6	19.1	17.7	17.8	18.1	18.1	17.1
646604	♂	16.9	18.6	18.1	19.7			
	♀	18.7	18.7	17.1	11.8			
646651	♂	19.0	17.8	18.4	17.7			
	♀	19.1	18.1	18.1	17.1			
646552a	♂							
	♀							
646606	♂	17.8	18.5	18.9	18.1			
	♀	18.1	17.0	16.9	15.8			
646557	♂	18.8	20.1	20.1	19.9			
	♀	18.6	18.6	18.4	18.5			
646591	♂	20.1	19.8	18.6	19.3			
	♀	18.8	18.5	20.0	19.4			
646544	♂	23.1	22.3	23.8	20.5			
	♀	20.9	20.3	22.8	19.8			
646646	♂	12.6	17.4	18.1	15.3			
	♀	15.3	16.6	15.4	14.3			
646520a	♂							
	♀							
646569	♂	15.4	17.1	14.7	13.7			
	♀	15.4	14.0	13.8	13.6			
646654	♂	20.2	20.7	21.2	19.8			
	♀	19.4	19.3	19.0	20.2			
646668	♂	18.1	19.4	21.0	20.3			
	♀	19.9	20.1	16.7	17.7			

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	7
646638	♂	19.7	19.8	17.5	19.3			
	♀	18.5	18.2	15.1	16.6			
646559	♂	19.3	20.6	20.0	17.3			
	♀	19.1	18.4	18.6	19.7			
646598 ^a	♂							
	♀							
646561	♂	22.8	22.8	22.4	23.3	23.7	23.4	
	♀	21.9						
646573 ^a	♂							
	♀							
646504	♂	16.7	17.0	18.3	17.1	17.6		
	♀	16.3	16.9	16.4				
646587 ^a	♂							
	♀							
646631 ^a	♂							
	♀							
646529	♂	18.9	19.3	19.1	20.2	20.0		
	♀	18.4	17.7	19.5				
646603	♂	16.8	18.1	15.7	16.7			
	♀	15.1	15.2	17.7	13.4			
646554 ^a	♂							
	♀							
646579	♂	17.3	17.5	17.7	13.9			
	♀	15.8	16.4	15.4	17.1			
646564 ^a	♂							
	♀							
646672	♂	22.6	23.6	24.1	23.8			
	♀	22.0	23.3	22.8	23.5			
646584 ^a	♂							
	♀							
646543	♂	19.8	19.5	20.8				
	♀	19.3	16.8	21.0	20.2	19.8		
646596	♂	15.0	17.9	17.7	17.6			
	♀	15.0	16.7	17.2	17.2			
646558 ^a	♂							
	♀							
646670 ^a	♂							
	♀							
646553	♂	20.8	21.1					
	♀	19.1	18.6	18.1	18.7	18.4	18.2	

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	6	7
646547	♂	8.70	14.3	16.9	9.40			
	♀	13.5	12.3	10.6	12.0			
646666 ^a	♂							
	♀							
646607	♂	8.30	9.50	8.10				
	♀	10.7	7.70					
646524 ^a	♂							
	♀							
646600	♂	15.0	15.0	18.1	18.4			
	♀	11.2	18.2	16.9	16.7			
646648	♂	17.4	18.9	19.0	19.3	19.7	20.9	
	♀	18.7	17.8					
646594	♂	19.5	19.4	19.5	17.2			
	♀	14.0	14.8	17.0	17.6			
646546	♂	17.5	16.5	17.4	16.6			
	♀	17.3	16.7	18.0	15.9			
646661 ^a	♂							
	♀							
646671	♂	12.7	17.6	13.6				
	♀	15.7	16.8	15.3	12.3	13.0		
646521	♂	18.5	18.8					
	♀	18.4	18.3	18.6	17.0	12.9	17.6	
646590 ^a	♂							
	♀							
646645	♂	19.8	18.1	17.6	12.4			
	♀	17.2	18.2	17.3	10.0			
646555 ^a	♂							
	♀							
646605 ^a	♂							
	♀							
646589 ^a	♂							
	♀							
646615	♂	17.3	20.5	20.6	20.4			
	♀	20.0	18.6	19.4	19.8			
646527 ^a	♂							
	♀							
646647	♂	15.3	16.9	15.7	15.2	16.3	17.3	
	♀	14.0	15.0					
646675 ^a	♂							
	♀							

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

Group: VIII-0

Dose: 500 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646662	♂	11.2	10.4	7.20	8.10			
	♀	9.80	8.60					
646583 ^a	♂							
	♀							
646623 ^f	♂							
	♀	7.50						
646619 ^e	♂							
	♀							
646539	♂	6.60						
	♀	5.90	6.60	5.70				
646628 ^a	♂							
	♀							
646616 ^a	♂							
	♀							
646563 ^a	♂							
	♀							
646641	♂	7.70	10.1	9.10				
	♀	8.60	7.10	8.10	8.60			
646572	♂	6.00	6.10					
	♀	4.80	5.40	5.80				
646512	♂	13.6	12.1	10.4	14.7	11.1		
	♀	12.9	12.4					
646566	♂	9.20	13.6	11.3	10.5			
	♀	11.4	12.5	10.2	12.6			
646570 ^a	♂							
	♀							
646602	♂	16.1	11.9	14.0				
	♀	13.1	12.3					
646582 ^a	♂							
	♀							
646655	♂	9.90	7.90					
	♀	11.2	9.50					
646663	♂	11.4	9.50	11.2	12.2			
	♀	15.0	7.30	13.4	8.00			
646640 ^d	♂							
	♀							
646574 ^e	♂							
	♀							
646532	♂	14.3	14.3	12.1	16.1			
	♀	14.7	16.5	15.8	8.70			

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

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646653	♂	38.7	39.2	39.9	39.7			
	♀	36.6	38.8	39.4	40.0			
646575	♂	37.4	37.7	39.3				
	♀	36.5	38.8	35.4	35.6	37.6		
646585 ^a	♂							
	♀							
646622	♂	37.3	38.2	40.0	37.6			
	♀	36.9	35.7	36.5	37.4			
646550	♂	32.0	32.1	32.7	32.9			
	♀	30.9	31.4	30.6	29.1			
646526	♂	43.5	43.3	43.1	42.8	43.8		
	♀	41.6	41.7	42.3				
646503	♂	42.3	43.9	40.0	44.3			
	♀	40.3	39.4	37.6	41.2			
646644	♂	37.4						
	♀	37.2	39.8	37.6	39.4	37.8	37.3	36.9
646604	♂	38.9	38.9	38.1	37.2			
	♀	38.4	29.5	38.0	35.7			
646651	♂	35.9	38.7	36.4	38.0			
	♀	35.6	38.5	37.3	39.1			
646552 ^a	♂							
	♀							
646606	♂	38.3	39.5	37.4	37.4			
	♀	36.8	37.8	35.9	35.2			
646557	♂	35.9	38.5	38.9	37.4			
	♀	36.9	36.6	36.6	36.8			
646591	♂	42.0	40.5	43.1	41.0			
	♀	39.1	42.9	39.8	41.4			
646544	♂	44.0	46.0	42.8	40.7			
	♀	43.1	40.3	40.9	38.0			
646646	♂	36.9	34.7	38.6	29.0			
	♀	33.6	33.3	33.4	35.5			
646520 ^a	♂							
	♀							
646569	♂	30.3	36.3	33.5	34.2			
	♀	33.0	33.7	30.0	29.0			
646654	♂	40.5	41.4	42.4	41.5			
	♀	38.5	38.7	41.7	39.6			
646668	♂	40.5	42.4	38.9	41.1			
	♀	41.6	41.6	37.1	38.2			

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

Group: IV-0

Dose: 25 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646638	♂	38.7	38.8	36.4	37.9			
	♀	32.1	33.5	37.4	38.8			
646559	♂	38.9	36.2	38.0	36.4			
	♀	36.5	36.1	36.3	37.2			
646598 ^a	♂							
	♀							
646561	♂	42.6	43.4	42.1	41.5	42.3	42.6	
	♀	39.8						
646573 ^a	♂							
	♀							
646504	♂	34.5	38.0	36.4	35.5	35.1		
	♀	34.8	34.3	33.8				
646587 ^a	♂							
	♀							
646631 ^a	♂							
	♀							
646529	♂	39.8	37.3	39.9	40.5	40.5		
	♀	37.6	38.3	35.4				
646603	♂	36.0	37.8	36.3	35.2			
	♀	31.2	34.0	34.3	37.8			
646554 ^a	♂							
	♀							
646579	♂	35.4	31.9	36.4	35.1			
	♀	32.9	35.4	33.6	34.4			
646564 ^a	♂							
	♀							
646672	♂	45.2	46.1	45.9	47.0			
	♀	45.3	44.8	46.2	42.4			
646584 ^a	♂							
	♀							
646543	♂	37.7	38.6	39.0				
	♀	39.1	38.6	37.0	37.6	33.4		
646596	♂	37.4	36.6	35.9	33.6			
	♀	32.2	35.3	34.4	34.8			
646558 ^a	♂							
	♀							
646670 ^a	♂							
	♀							
646553	♂	39.0	41.8					
	♀	35.4	38.7	37.0	36.0	36.1	36.2	

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	6	7
646547	♂	41.5	22.1					
	♀	24.6						
646666 ^a	♂							
	♀							
646607 ^e	♂							
	♀							
646524 ^a	♂							
	♀							
646600	♂	37.4	30.0	38.8	35.1			
	♀	38.7	37.2	37.7				
646648	♂	40.0	38.7	41.9	37.5	38.8	37.2	
	♀	36.5	38.8					
646594	♂	42.7	42.0	42.6	40.4			
	♀	39.2	40.1					
646546	♂	35.3	34.5	34.2	35.4			
	♀	35.8	32.7	35.1	35.2			
646661 ^a	♂							
	♀							
646671	♂	37.8	42.1					
	♀	36.9	38.5	40.1	12.2			
646521	♂	35.8	37.0					
	♀	36.6	34.4	27.4	36.0	35.9	36.4	
646590 ^a	♂							
	♀							
646645	♂	36.2	37.9	38.6				
	♀	35.9	35.6	35.8	16.2			
646555 ^a	♂							
	♀							
646605 ^a	♂							
	♀							
646589 ^a	♂							
	♀							
646615	♂	39.1	39.1	38.9	35.2			
	♀	36.7	35.7	38.5	38.8			
646527 ^a	♂							
	♀							
646647	♂	35.2	38.2	32.5	35.4	36.7	34.5	
	♀	35.0	32.9					
646675 ^a	♂							
	♀							

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

Group: VIII-0 Dose: 500 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646662 ^e	♂							
	♀							
646583 ^a	♂							
	♀							
646623 ^e	♂							
	♀							
646619 ^e	♂							
	♀							
646539 ^e	♂							
	♀							
646628 ^a	♂							
	♀							
646616 ^a	♂							
	♀							
646563 ^a	♂							
	♀							
646641 ^e	♂							
	♀							
646572 ^e	♂							
	♀							
646512 ^e	♂							
	♀							
646566	♂	22.9	13.4					
	♀	18.1	17.4					
646570 ^a	♂							
	♀							
646602 ^e	♂							
	♀							
646582 ^a	♂							
	♀							
646655 ^e	♂							
	♀							
646663	♂	27.0	21.9	26.9	16.2			
	♀	29.5	26.6					
646640 ^d	♂							
	♀							
646574 ^e	♂							
	♀							
646532	♂	29.1						
	♀	25.3	19.4	11.7				

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

Group: II-0

Dose: 0 mg/kg/day

Animal Number	Pup Sex	Pup Number						
		1	2	3	4	5	6	7
646653	♂	70.2	69.0	66.2	69.2			
	♀	66.3	68.1	62.0	68.7			
646575	♂	67.5	66.6	59.2				
	♀	64.9	62.7	61.9	66.6	61.5		
646585 ^a	♂							
	♀							
646622	♂	59.0	62.0	57.8	64.5			
	♀	57.8	59.4	57.3	58.8			
646550	♂	59.9	60.7	57.9	59.4			
	♀	52.1	57.1	58.2	52.6			
646526	♂	76.5	72.0	70.5	71.5	74.1		
	♀	69.9	68.4	70.3				
646503	♂	69.6	65.7	76.1	74.8			
	♀	70.5	64.7	70.2	62.4			
646644	♂	52.5						
	♀	51.6	51.3	52.4	49.6	49.0	50.8	49.4
646604	♂	62.5	61.2	57.9	61.7			
	♀	45.7	57.4	59.1	58.7			
646651	♂	67.1	66.2	63.0	64.4			
	♀	67.4	66.4	64.7	67.3			
646552 ^a	♂							
	♀							
646606	♂	59.8	62.9	61.8	56.3			
	♀	58.1	55.4	55.1	56.7			
646557	♂	69.9	67.0	69.1	68.7			
	♀	65.7	63.7	63.9	64.5			
646591	♂	67.7	66.1	68.7	71.7			
	♀	69.9	64.2	63.4	63.7			
646544	♂	75.2	69.6	71.8	66.5			
	♀	70.4	63.0	59.6	65.1			
646646	♂	46.0	63.8	53.7	59.7			
	♀	48.4	54.4	55.3	54.2			
646520 ^a	♂							
	♀							
646569	♂	53.4	57.5	55.9	55.0			
	♀	54.4	47.3	53.4	48.3			
646654	♂	63.8	66.7	67.0	69.6			
	♀	65.5	60.8	63.2	63.7			
646668	♂	68.5	72.8	65.3	68.1			
	♀	69.1	64.2	65.5	71.2			

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	7
646638	♂	61.4	59.0	59.6	60.9			
	♀	52.1	60.3	54.8	59.3			
646559	♂	59.8	65.7	60.6	55.1			
	♀	59.6	61.3	58.6	60.7			
646598 ^a	♂							
	♀							
646561	♂	74.4	73.1	70.2	72.5	73.0	71.1	
	♀	66.1						
646573 ^a	♂							
	♀							
646504	♂	58.2	59.9	63.8	61.3	59.6		
	♀	57.7	59.2	56.5				
646587 ^a	♂							
	♀							
646631 ^a	♂							
	♀							
646529	♂	62.4	60.2	59.2	62.4	59.5		
	♀	54.2	54.8	57.9				
646603	♂	58.5	58.5	62.0	63.1			
	♀	63.4	56.0	51.9	55.9			
646554 ^a	♂							
	♀							
646579	♂	57.1	52.6	54.3	58.7			
	♀	52.7	52.5	53.2	53.6			
646564 ^a	♂							
	♀							
646672	♂	75.1	69.8	64.6	72.0			
	♀	69.6	65.4	69.7	69.8			
646584 ^a	♂							
	♀							
646543	♂	64.2	66.3	62.5				
	♀	60.1	53.4	63.7	59.6	62.0		
646596	♂	63.3	53.7	61.0	60.6			
	♀	57.2	57.8	57.4	35.9			
646558 ^a	♂							
	♀							
646670 ^a	♂							
	♀							
646553	♂	58.0	54.5					
	♀	48.2	50.6	52.1	48.5	48.3	48.9	

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	6	7
646547g	♂	29.0	52.7					
	♀							
646666a	♂							
	♀							
646607e	♂							
	♀							
646524a	♂							
	♀							
646600	♂	61.1	64.7	49.5	57.4			
	♀	61.2	58.8	63.6				
646648	♂	63.5	68.1	63.8	60.6	59.5	58.8	
	♀	59.7	55.0					
646594	♂	71.6	68.9	68.3	71.1			
	♀	67.3	64.0					
646546	♂	55.0	45.8	57.7	54.1			
	♀	54.1	54.7	56.5	55.9			
646661a	♂							
	♀							
646671	♂	67.1	62.8					
	♀	63.0	59.5	64.2				
646521	♂	63.2	57.0					
	♀	57.9	61.0	58.2	56.0	45.6	58.2	
646590a	♂							
	♀							
646645	♂	63.5	65.8	64.1				
	♀	61.7	61.1	24.1	62.0			
646555a	♂							
	♀							
646605a	♂							
	♀							
646589a	♂							
	♀							
646615	♂	60.6	68.9	66.3	69.1			
	♀	64.6	66.0	59.0	68.4			
646527a	♂							
	♀							
646647	♂	59.5	56.5	54.7	56.1	61.7	63.9	
	♀	54.9	56.9					
646675a	♂							
	♀							

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

Group: VIII-0 Dose: 500 mg/kg/day

Animal Number	Pup Sex	<u>Pup Number</u>						
		1	2	3	4	5	6	7
646662 ^e	♂							
	♀							
646583 ^a	♂							
	♀							
646623 ^e	♂							
	♀							
646619 ^e	♂							
	♀							
646539 ^e	♂							
	♀							
646628 ^a	♂							
	♀							
646616 ^a	♂							
	♀							
646563 ^a	♂							
	♀							
646641 ^e	♂							
	♀							
646572 ^e	♂							
	♀							
646512 ^e	♂							
	♀							
646566	♂	34.1						
	♀	32.5	28.2					
646570 ^a	♂							
	♀							
646602 ^e	♂							
	♀							
646582 ^a	♂							
	♀							
646655 ^e	♂							
	♀							
646663	♂	38.3	38.0	40.3				
	♀	42.1	42.6					
646640 ^d	♂							
	♀							
646574 ^e	♂							
	♀							
646532	♂	27.9						
	♀	18.3						

APPENDIX HH
REPRODUCTIVE TOXICOLOGY
INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

REPRODUCTIVE TOXICOLOGY

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

EXPLANATORY NOTES

Footnotes

- a* All pups were found dead on Lactation Day 0.

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

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

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
646653			NO ABNORMALITIES DETECTED
646575			NO ABNORMALITIES DETECTED
646622			NO ABNORMALITIES DETECTED
646550			NO ABNORMALITIES DETECTED
646526			NO ABNORMALITIES DETECTED
646503			NO ABNORMALITIES DETECTED
646644			NO ABNORMALITIES DETECTED
646604			NO ABNORMALITIES DETECTED
646651	DAY 0	1 OF 16	PARTIALLY CANNIBALIZED RIGHT REAR LEG(S)
		1 OF 16	PARTIALLY CANNIBALIZED RIGHT REAR PAW(S)
		1 OF 16	PARTIALLY CANNIBALIZED TAIL
	DAY 4 PRE	1 OF 16	PARTIALLY CANNIBALIZED RIGHT REAR LEG(S)
		1 OF 16	PARTIALLY CANNIBALIZED RIGHT REAR PAW(S)
		1 OF 16	PARTIALLY CANNIBALIZED TAIL
	LITTER SUMMARY:	1	PARTIALLY CANNIBALIZED RIGHT REAR LEG(S)
		1	PARTIALLY CANNIBALIZED RIGHT REAR PAW(S)
		1	PARTIALLY CANNIBALIZED TAIL
646606			NO ABNORMALITIES DETECTED
646557			NO ABNORMALITIES DETECTED
646591			NO ABNORMALITIES DETECTED
646544			NO ABNORMALITIES DETECTED
646646			NO ABNORMALITIES DETECTED
646569			NO ABNORMALITIES DETECTED
646654			NO ABNORMALITIES DETECTED
646668			NO ABNORMALITIES DETECTED

INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

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

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
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646638	NO	ABNORMALITIES DETECTED	
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646559	NO	ABNORMALITIES DETECTED	
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646561	NO	ABNORMALITIES DETECTED	
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646504	NO	ABNORMALITIES DETECTED	
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646529	NO	ABNORMALITIES DETECTED	
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646603	NO	ABNORMALITIES DETECTED	
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646579	NO	ABNORMALITIES DETECTED	
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646672	NO	ABNORMALITIES DETECTED	
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646543	NO	ABNORMALITIES DETECTED	
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646596	NO	ABNORMALITIES DETECTED	
--------	----	------------------------	--

646553	NO	ABNORMALITIES DETECTED	
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INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

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

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
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646547	NO	ABNORMALITIES	DETECTED
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646607	NO	ABNORMALITIES	DETECTED
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646600	NO	ABNORMALITIES	DETECTED
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646648	NO	ABNORMALITIES	DETECTED
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646594	NO	ABNORMALITIES	DETECTED
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646546	NO	ABNORMALITIES	DETECTED
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646671	NO	ABNORMALITIES	DETECTED
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646521	NO	ABNORMALITIES	DETECTED
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646645	NO	ABNORMALITIES	DETECTED
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646615	NO	ABNORMALITIES	DETECTED
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646647	NO	ABNORMALITIES	DETECTED
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INDIVIDUAL LITTER CLINICAL OBSERVATIONS: F₁ GENERATION

GROUP: VIII-0

DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	LACTATION DAY	SIGN INCIDENCE	OBSERVATIONS
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646662 NO ABNORMALITIES DETECTED

646623 NO ABNORMALITIES DETECTED

646619 NO ABNORMALITIES DETECTED

646539 NO ABNORMALITIES DETECTED

646641 NO ABNORMALITIES DETECTED

646572 NO ABNORMALITIES DETECTED

646512 NO ABNORMALITIES DETECTED

646566 NO ABNORMALITIES DETECTED

646602 NO ABNORMALITIES DETECTED

646655 NO ABNORMALITIES DETECTED

646663 NO ABNORMALITIES DETECTED

646574^a

646532	DAY 21	1 OF 2	STAINED PERINEUM YELLOW
		1 OF 2	WET PERINEUM
		1 OF 2	LETHARGY
		1 OF 2	WEAK

LITTER SUMMARY:	1	STAINED PERINEUM
	1	WET PERINEUM
	1	LETHARGY
	1	WEAK

DAY 21 PUP DATA:	PUP:	
	a	STAINED PERINEUM YELLOW
		WET PERINEUM
		LETHARGY
		WEAK

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.

Footnotes

- a* Sacrificed by design Test Day 15.
- b* Sacrificed by design on Test Day 13.
- c* Found dead on Test Day 3.
- d* Found dead on Test Day 5.
- e* Found dead on Test Day 2.

Abbreviations

--- = No data.

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						
649992	69.2	112.2	173.6	241.3	303.5	354.7
649993	59.2	108.5	174.3	252.0	323.3	388.4
649994	64.5	107.7	173.6	239.5	304.2	365.3
649995	59.4	99.3	159.7	218.1	282.9	352.3
649996	74.1	120.8	186.9	254.6	326.0	396.0
649997	74.8	123.2	190.2	254.0	318.5	380.9
649998	52.5	97.1	154.1	225.7	290.7	346.7
649999	61.7	110.6	175.4	246.6	310.5	370.8
650000	64.4	115.0	180.2	252.1	319.5	397.1
650001	56.3	98.3	162.1	228.0	287.0	332.7
650002	68.7	112.8	179.1	244.1	314.6	382.6
650003	71.7	118.7	188.5	267.8	336.0	395.6
650004	66.5	110.4	176.1	232.0	278.7	329.9
650005	59.7	102.6	164.6	239.9	303.3	369.1
650006	55.0	87.0	134.0	190.5	247.4	304.8
650007	69.6	116.3	179.0	247.2	310.2	366.1
650008	68.1	115.6	179.9	244.6	306.3	367.7

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						
650009	60.9	103.0	164.6	230.3	288.7	338.8
650010	55.1	105.7	168.2	234.3	294.5	352.6
650011	71.1	116.4	187.6	259.2	328.9	393.6
650012	59.6	105.5	176.6	252.8	326.8	400.6
650013	59.5	101.3	164.6	230.9	301.1	360.6
650014	63.1	101.6	160.4	222.0	283.1	348.8
650015	58.7	105.4	158.3	215.4	272.2	327.6
650016	72.0	120.6	190.8	268.0	338.3	410.1
650017	62.5	102.5	160.7	226.4	293.8	344.4
650018	60.6	103.6	167.2	230.6	286.1	346.8
650019	54.5	107.2	167.4	233.8	295.5	354.7

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						
650020	52.7	87.5	136.6	196.0	250.9	309.0
650022	57.4	92.7	160.3	234.8	299.6	356.5
650023	58.8	103.3	167.1	228.6	286.1	346.2
650024	71.1	114.1	183.0	254.3	330.1	411.0
650025	54.1	101.9	160.8	215.3	272.5	332.5
650026	62.8	105.6	171.2	240.2	302.5	368.8
650027	57.0	99.5	132.2	198.7	253.3	307.7
650028	64.1	110.6	173.7	243.2	306.7	365.7
650029	69.1	116.3	182.2	250.3	318.0	367.0
650030	63.9	103.6	163.1	231.9	299.2	359.7

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ MALE RATS

GROUP: VII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
650032 ^a	34.1	68.0	116.5	---	---	---
650035 ^b	40.3	72.9	---	---	---	---
650036 ^c	27.9	---	---	---	---	---

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						
650043	68.7	114.5	161.2	186.9	213.4	225.7
650044	61.5	111.8	159.8	190.5	201.1	227.2
650045	58.8	87.4	124.2	152.4	178.4	205.0
650046	52.6	87.3	128.4	159.8	169.9	197.4
650047	70.3	123.4	172.2	199.6	236.9	260.7
650048	62.4	98.8	139.5	159.8	182.4	194.9
650049	49.4	92.9	134.3	167.5	187.1	208.7
650050	58.7	104.2	147.2	181.9	216.3	238.3
650051	67.3	112.9	153.0	176.6	211.1	231.7
650052	56.7	90.7	131.8	168.4	190.0	217.3
650053	64.5	98.5	145.5	176.1	191.6	214.1
650054	63.7	101.9	138.8	174.4	202.9	224.5
650055	65.1	107.1	150.0	179.9	201.1	221.0
650056	54.2	93.3	144.3	179.2	201.4	228.2
650057	48.3	78.4	109.7	143.4	169.9	185.3
650058	63.7	106.3	141.5	177.1	195.9	210.4
650059	71.2	122.3	174.0	218.1	244.9	268.4

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						
650060	59.3	95.3	133.5	163.0	184.8	197.0
650061	60.7	77.5	131.1	173.2	217.1	239.7
650062	66.1	117.3	178.9	211.7	235.4	247.3
650063	56.5	95.7	135.2	163.3	190.9	211.8
650064	57.9	101.0	139.1	175.4	201.0	224.6
650065	55.9	96.5	138.1	177.8	197.0	205.7
650066	53.6	80.6	127.9	171.6	200.4	221.6
650067	69.8	105.0	148.6	177.4	200.2	217.9
650068	62.0	98.8	137.1	171.6	194.0	207.9
650069	35.9	86.2	134.6	175.0	206.6	228.6
650070	48.9	90.2	133.0	176.6	203.8	227.1

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						
650073	63.6	98.5	141.6	182.5	208.0	220.8
650074	55.0	89.0	126.3	160.0	183.4	196.9
650075	64.0	102.9	151.5	195.9	233.2	255.8
650076	55.9	93.8	140.8	181.0	211.9	241.9
650077	64.2	100.5	137.6	170.4	189.1	208.6
650078	58.2	96.0	131.8	161.7	192.7	218.6
650079	62.0	97.6	150.3	187.7	225.1	258.9
650080	68.4	119.0	154.5	183.9	204.0	232.3
650081	56.9	93.1	138.5	167.9	193.1	212.1

INDIVIDUAL BODY WEIGHTS (grams) OF F₁ FEMALE RATS

GROUP: VIII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1	8	15	22	29	36
ANIMAL NUMBER						
650083 ^d	28.2	---	---	---	---	---
650086 ^b	42.6	71.1	---	---	---	---
650087 ^e	18.3	---	---	---	---	---

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.

Footnotes

- a* Sacrificed by design Test Day 15.
- b* Sacrificed by design on Test Day 13.
- c* Found dead on Test Day 3.
- d* Found dead on Test Day 5.
- e* Found dead on Test Day 2.

Abbreviations

--- = No data.

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						
649992	43.0	61.4	67.7	62.2	51.2	285.5
649993	49.3	65.8	77.7	71.3	65.1	329.2
649994	43.2	65.9	65.9	64.7	61.1	300.8
649995	39.9	60.4	58.4	64.8	69.4	292.9
649996	46.7	66.1	67.7	71.4	70.0	321.9
649997	48.4	67.0	63.8	64.5	62.4	306.1
649998	44.6	57.0	71.6	65.0	56.0	294.2
649999	48.9	64.8	71.2	63.9	60.3	309.1
650000	50.6	65.2	71.9	67.4	77.6	332.7
650001	42.0	63.8	65.9	59.0	45.7	276.4
650002	44.1	66.3	65.0	70.5	68.0	313.9
650003	47.0	69.8	79.3	68.2	59.6	323.9
650004	43.9	65.7	55.9	46.7	51.2	263.4
650005	42.9	62.0	75.3	63.4	65.8	309.4
650006	32.0	47.0	56.5	56.9	57.4	249.8
650007	46.7	62.7	68.2	63.0	55.9	296.5
650008	47.5	64.3	64.7	61.7	61.4	299.6

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						
650009	42.1	61.6	65.7	58.4	50.1	277.9
650010	50.6	62.5	66.1	60.2	58.1	297.5
650011	45.3	71.2	71.6	69.7	64.7	322.5
650012	45.9	71.1	76.2	74.0	73.8	341.0
650013	41.8	63.3	66.3	70.2	59.5	301.1
650014	38.5	58.8	61.6	61.1	65.7	285.7
650015	46.7	52.9	57.1	56.8	55.4	268.9
650016	48.6	70.2	77.2	70.3	71.8	338.1
650017	40.0	58.2	65.7	67.4	50.6	281.9
650018	43.0	63.6	63.4	55.5	60.7	286.2
650019	52.7	60.2	66.4	61.7	59.2	300.2

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						
650020	34.8	49.1	59.4	54.9	58.1	256.3
650022	35.3	67.6	74.5	64.8	56.9	299.1
650023	44.5	63.8	61.5	57.5	60.1	287.4
650024	43.0	68.9	71.3	75.8	80.9	339.9
650025	47.8	58.9	54.5	57.2	60.0	278.4
650026	42.8	65.6	69.0	62.3	66.3	306.0
650027	42.5	32.7	66.5	54.6	54.4	250.7
650028	46.5	63.1	69.5	63.5	59.0	301.6
650029	47.2	65.9	68.1	67.7	49.0	297.9
650030	39.7	59.5	68.8	67.3	60.5	295.8

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ MALE RATS

GROUP: VII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
650032 ^a	33.9	48.5	---	---	---	---
650035 ^b	32.6	---	---	---	---	---
650036 ^c	---	---	---	---	---	---

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						
650043	45.8	46.7	25.7	26.5	12.3	157.0
650044	50.3	48.0	30.7	10.6	26.1	165.7
650045	28.6	36.8	28.2	26.0	26.6	146.2
650046	34.7	41.1	31.4	10.1	27.5	144.8
650047	53.1	48.8	27.4	37.3	23.8	190.4
650048	36.4	40.7	20.3	22.6	12.5	132.5
650049	43.5	41.4	33.2	19.6	21.6	159.3
650050	45.5	43.0	34.7	34.4	22.0	179.6
650051	45.6	40.1	23.6	34.5	20.6	164.4
650052	34.0	41.1	36.6	21.6	27.3	160.6
650053	34.0	47.0	30.6	15.5	22.5	149.6
650054	38.2	36.9	35.6	28.5	21.6	160.8
650055	42.0	42.9	29.9	21.2	19.9	155.9
650056	39.1	51.0	34.9	22.2	26.8	174.0
650057	30.1	31.3	33.7	26.5	15.4	137.0
650058	42.6	35.2	35.6	18.8	14.5	146.7
650059	51.1	51.7	44.1	26.8	23.5	197.2

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						
650060	36.0	38.2	29.5	21.8	12.2	137.7
650061	16.8	53.6	42.1	43.9	22.6	179.0
650062	51.2	61.6	32.8	23.7	11.9	181.2
650063	39.2	39.5	28.1	27.6	20.9	155.3
650064	43.1	38.1	36.3	25.6	23.6	166.7
650065	40.6	41.6	39.7	19.2	8.7	149.8
650066	27.0	47.3	43.7	28.8	21.2	168.0
650067	35.2	43.6	28.8	22.8	17.7	148.1
650068	36.8	38.3	34.5	22.4	13.9	145.9
650069	50.3	48.4	40.4	31.6	22.0	192.7
650070	41.3	42.8	43.6	27.2	23.3	178.2

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						
650073	34.9	43.1	40.9	25.5	12.8	157.2
650074	34.0	37.3	33.7	23.4	13.5	141.9
650075	38.9	48.6	44.4	37.3	22.6	191.8
650076	37.9	47.0	40.2	30.9	30.0	186.0
650077	36.3	37.1	32.8	18.7	19.5	144.4
650078	37.8	35.8	29.9	31.0	25.9	160.4
650079	35.6	52.7	37.4	37.4	33.8	196.9
650080	50.6	35.5	29.4	20.1	28.3	163.9
650081	36.2	45.4	29.4	25.2	19.0	155.2

INDIVIDUAL BODY WEIGHT GAINS (grams) OF F₁ FEMALE RATS

GROUP: VIII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
650083 ^d	---	---	---	---	---	---
650086 ^b	28.5	---	---	---	---	---
650087 ^e	---	---	---	---	---	---

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.

Footnotes

- a* Food consumption was inadvertently not measured on Test Day 1.
- b* Sacrificed by design Test Day 15.
- c* Sacrificed by design on Test Day 13.
- d* Found dead on Test Day 3.
- e* Found dead on Test Day 5.
- f* Found dead on Test Day 2.

Abbreviations

--- = No data.

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						
649992	12.5	20.1	26.5	29.0	30.5	23.7
649993	12.1	19.3	26.3	29.8	33.3	24.2
649994	13.1	21.6	28.6	32.2	34.3	26.0
649995	12.1	21.0	25.7	29.8	43.1	26.3
649996	13.9	20.9	26.3	31.9	35.4	25.7
649997	13.5	22.0	27.4	29.1	30.4	24.5
649998	11.6	17.9	24.8	26.8	29.2	22.1
649999	--- ^a	22.5	29.4	32.7	35.8	--- ^a
650000	14.5	21.8	27.3	31.0	36.8	26.3
650001	11.5	18.5	23.8	26.7	27.2	21.6
650002	13.1	20.2	24.8	29.1	33.6	24.1
650003	14.3	22.4	29.5	31.0	34.9	26.4
650004	12.3	19.7	24.2	26.0	28.8	22.2
650005	12.5	18.2	26.0	27.8	31.8	23.2
650006	10.4	16.0	20.6	23.0	25.4	19.1
650007	12.8	19.6	25.3	27.7	29.9	23.1
650008	12.7	19.8	24.6	27.2	31.7	23.2

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						
650009	11.7	18.3	23.2	25.5	26.8	21.1
650010	12.5	19.0	24.6	28.3	31.0	23.1
650011	12.1	20.2	24.9	26.6	31.6	23.1
650012	12.3	20.5	26.6	32.4	37.7	25.9
650013	12.7	19.9	23.9	28.2	30.4	23.0
650014	11.2	16.5	22.0	25.7	28.2	20.7
650015	12.7	19.0	22.4	25.9	27.1	21.4
650016	13.2	21.7	28.3	31.5	33.3	25.6
650017	12.0	19.0	26.1	28.0	29.6	22.9
650018	12.5	21.1	28.0	29.2	32.0	24.5
650019	---a	20.1	25.1	28.4	31.0	---a

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						
650020	9.2	15.3	19.4	22.7	25.1	18.3
650022	9.9	19.6	28.1	29.8	33.2	24.1
650023	11.9	18.7	24.1	27.0	29.6	22.3
650024	13.1	20.8	26.9	30.3	35.3	25.3
650025	13.4	19.7	22.9	24.8	29.7	22.1
650026	11.3	19.8	27.6	29.2	33.3	24.2
650027	11.9	15.0	23.2	24.6	27.3	20.4
650028	13.3	21.3	28.8	31.0	32.8	25.4
650029	12.7	21.3	27.4	31.5	32.5	25.1
650030	12.6	19.3	25.2	29.9	32.7	23.9

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

GROUP: VII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
650032 ^b	6.8	16.0	---	---	---	---
650035 ^c	8.9	---	---	---	---	---
650036 ^d	---	---	---	---	---	---

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						
650043	13.5	20.0	19.2	21.4	21.4	19.1
650044	13.1	19.4	21.5	20.8	21.2	19.2
650045	10.5	15.2	18.3	20.0	20.0	16.8
650046	11.5	19.8	19.6	19.3	20.1	18.0
650047	14.7	19.9	21.2	21.4	24.1	20.2
650048	11.6	16.9	16.4	17.7	17.1	15.9
650049	11.0	14.7	18.7	17.0	18.0	15.9
650050	--- ^a	17.5	20.5	22.4	26.6	--- ^a
650051	13.0	17.2	19.0	20.9	21.9	18.4
650052	10.7	14.9	16.7	16.9	18.2	15.5
650053	11.7	17.2	18.8	17.8	19.0	16.9
650054	12.7	17.1	20.6	20.5	21.2	18.4
650055	12.7	18.2	18.0	17.8	18.4	17.0
650056	10.5	17.5	18.6	19.5	20.6	17.4
650057	8.5	13.3	19.8	16.4	17.6	15.1
650058	11.7	17.2	19.2	18.4	18.4	17.0
650059	15.1	20.6	23.6	22.9	23.6	21.2

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						
650060	10.8	15.9	16.0	16.7	15.9	15.0
650061	6.5	17.7	21.7	24.3	24.3	18.9
650062	12.9	22.0	22.6	22.6	21.9	20.4
650063	11.7	16.7	18.4	19.6	19.2	17.1
650064	12.8	16.9	18.6	18.8	19.3	17.3
650065	12.0	16.6	18.2	18.0	17.6	16.5
650066	8.2	15.2	19.6	19.7	21.1	16.8
650067	11.6	15.8	17.5	18.5	18.2	16.3
650068	10.9	15.6	18.5	18.1	18.4	16.3
650069	10.8	16.4	20.0	22.2	23.8	18.6
650070	--- ^a	16.1	19.9	20.3	21.7	--- ^a

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						
650073	10.9	16.4	19.6	19.3	20.9	17.4
650074	9.3	14.7	16.9	17.3	18.5	15.3
650075	12.1	17.6	22.0	24.3	24.0	20.0
650076	11.6	17.5	19.7	21.2	23.1	18.6
650077	9.7	15.8	18.9	17.1	17.7	15.9
650078	11.0	15.4	18.1	19.5	19.3	16.7
650079	10.5	18.1	20.5	22.3	24.8	19.2
650080	13.8	17.9	18.8	19.0	20.7	18.1
650081	11.2	16.9	18.1	18.4	18.8	16.7

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

GROUP: VIII-1

DOSE: 500 MG/KG/DAY

DAYS ON TEST:	1-8	8-15	15-22	22-29	29-36	1-36
ANIMAL NUMBER						
650083 ^e	---	---	--	---	---	---
650086 ^c	8.0	---	---	---	---	---
650087 ^f	---	---	---	---	---	---

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
649992	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
649993	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
649994	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
649995	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
649996	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
649997	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
649998	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
649999	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
650000	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650001	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
650002	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24
650003	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650004	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650005	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
650006	PREPUTIAL SEPARATION COMPLETE ALOPECIA BOTH FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 40	27 36	27 40
650007	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
650008	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650009	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650010	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
650011	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	22	22
650012	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650013	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650014	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650015	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
650016	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650017	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650018	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650019	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650020	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	29	29
650022	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
650023	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650024	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	26	26
650025	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650026	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	27	27
650027	PREPUTIAL SEPARATION COMPLETE ALOPECIA RIGHT FRONT PAW(S) SACRIFICED BY DESIGN TEST DAY 40	25 40	25 40
650028	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	23	23
650029	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	25	25
650030	PREPUTIAL SEPARATION COMPLETE SACRIFICED BY DESIGN TEST DAY 40	24	24

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ MALE RATS

GROUP: VII-1 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650032	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 15		
650035	NO ABNORMALITIES DETECTED SACRIFICED BY DESIGN TEST DAY 13		
650036	NO ABNORMALITIES DETECTED FOUND DEAD TEST DAY 3		

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650043	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8
650044	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	9	9
650045	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
650046	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650047	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	9	9
650048	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650049	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	15	15
650050	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
650051	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650052	ALOPECIA BOTH FRONT PAW(S) VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8 13	22 13
650053	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
650054	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
650055	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	9	9
650056	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650057	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650058	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
650059	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650060	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
650061	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650062	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650063	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	15	15
650064	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650065	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8
650066	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	15	15
650067	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650068	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650069	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11
650070	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	11	11

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

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

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650073	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	14	14
650074	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
650075	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	15	15
650076	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	12	12
650077	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
650078	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	10	10
650079	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	13	13
650080	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	8	8
650081	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 40	9	9

INDIVIDUAL CLINICAL OBSERVATIONS IN F₁ FEMALE RATS

GROUP: VIII-1 DOSE: 500 MG/KG/DAY

ANIMAL NUMBER	OBSERVATION	FIRST DAY OBSERVED	LAST DAY OBSERVED
650083	NO ABNORMALITIES DETECTED FOUND DEAD TEST DAY 5		
650086	VAGINAL PATENCY COMPLETE SACRIFICED BY DESIGN TEST DAY 13	11	11
650087	STAINED PERINEUM YELLOW	1	1
	WET PERINEUM	1	1
	LETHARGY	1	1
	WEAK	1	1
	FOUND DEAD TEST DAY 2		