

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**C Number:** C54911

**Cage Range:** All

**Date Range:** All

**Reasons For Removal:** All

**Removal Date Range:** All

**Treatment Groups:** All

**Study Gender:** Female

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_001

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Intestine Large  
Kidney

Colon

Inflammation, Chronic  
Atrophy, Nos  
Fibrosis

Pelvis

Hyperplasia, Epithelial  
Inflammation, Chronic  
Nephropathy

Lymph node  
Pituitary gland

Mesenteric Lymph Node

Atrophy, Nos  
Cyst, Nos

Stomach  
Thyroid

Forestomach

Hyperplasia, Nos  
Hyperplasia, Focal

Unspecified  
Urinary bladder

Multiple Organs Nos

Hyperplasia, C Cell  
Inflammation, Suppurative  
Hyperplasia, Epithelial  
Inflammation, Chronic

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_002

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Blood vessel  
Heart  
Kidney

Aorta Nos

Mineralization  
Inflammation, Chronic  
Hyperplasia, Epithelial  
Inflammation, Chronic  
Inflammation, Suppurative

Pelvis

Medulla

Necrosis, Nos  
Nephropathy  
Nephrosis, Hydro

Lymph node  
Stomach

Mesenteric Lymph Node

Muscularis

Atrophy, Nos  
Degeneration, Nos

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_003

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel

Artery Nos

Degeneration, Hyaline

Aorta Nos

Mineralization

Artery Nos

Periarteritis

Heart

Fibrosis

Kidney

Atrophy, Nos

Pelvis

Fibrosis

Hyperplasia, Epithelial

Inflammation, Chronic

Inflammation, Suppurative

Mammary gland

Nephropathy

Pituitary gland

Hyperplasia, Cystic

Adenoma, Nos

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_004

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Blood vessel	Artery Nos	Periarteritis
Bone	Femur	Dysplasia, Fibrous
Heart		Fibrosis
Intestine Large	Cecum, Colon	Inflammation, Chronic
	Colon	Inflammation, Chronic
	Cecum, Colon	Inflammation, Suppurative
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
	Renal Lymph Node	Lymphangiectasis
Mammary gland		Hyperplasia, Cystic
Ovary		Cyst, Nos

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**PRIMARY CAUSE OF DEATH**

-

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**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_005

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Heart		Degeneration, Nos
		Inflammation, Chronic
Intestine Large	Colon	Inflammation, Suppurative
Kidney		Inflammation, Suppurative
	Papilla	Necrosis, Nos
		Nephropathy

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_006

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Intestine Large  
Kidney

Colon

Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_007

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Intestine Large  
Kidney

Colon

Inflammation, Suppurative  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Liver  
Uterus

Hepatocytes

Cytoplasmic Vacuolization  
Inflammation, Suppurative

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_008

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

**OBSERVATIONS**

Blood vessel	Artery Nos	Periarteritis
Bone	Femur	Dysplasia, Fibrous
Intestine Large	Cecum, Colon	Inflammation, Chronic
Kidney		Atrophy, Nos
		Cyst, Nos
	Pelvis	Hemorrhage
	Pelvis	Hyperplasia, Epithelial
		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
	Papilla	Thrombosis, Nos
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Inflammation, Suppurative
Pituitary gland		Hyperplasia, Nos
Stomach	Muscularis	Degeneration, Nos
Uterus	Endometrium	Hyperplasia, Epithelial

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_009

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Heart  
Kidney

Fibrosis  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy  
Nephrosis, Hydro  
Alveolar Macrophages  
Embolism, Nos  
Cyst, Nos

Lung

Ovary

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_010

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Intestine Large

Colon

Inflammation, Suppurative

Kidney

Papilla

Inflammation, Suppurative

Necrosis, Nos

Nephropathy

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_011

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Kidney

Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Lymph node

Mesenteric Lymph Node

Nephrosis, Hydro

Stomach

Glandular Stomach

Atrophy, Nos

Ulcer, Nos

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_012

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Blood vessel

Artery Nos

Degeneration, Hyaline

Coronary Artery Nos

Necrosis, Focal

Artery Nos

Periarteritis

Bone

Femur

Dysplasia, Fibrous

Heart

Fibrosis

Intestine Small

Mesentery Nos

Necrosis, Fat

Kidney

Pelvis

Calculus, Microscopic Examination

Pelvis

Hyperplasia, Epithelial

Inflammation, Chronic

Inflammation, Suppurative

Nephropathy

Nephrosis, Hydro

Pigmentation, Nos

Transitional-Cell Carcinoma

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Mammary gland

Hyperplasia, Cystic

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_013

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Medulla	Hyperplasia, Focal Pheochromocytoma
Blood vessel	Aorta Nos Artery Nos	Mineralization Mineralization
Bone	Femur	Dysplasia, Fibrous
Heart		Fibrosis
Intestine Large	Cecum, Colon	Inflammation, Chronic
Kidney	Pelvis	Hyperplasia, Epithelial Inflammation, Chronic Nephropathy
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic Hyperplasia, Nos
Ovary		Cyst, Nos
Pituitary gland		Hyperplasia, Nos
Salivary gland		Retention Of Content
Stomach	Muscularis Glandular Stomach	Degeneration, Nos Mineralization
	Muscularis	Mineralization
Unspecified	Multiple Organs Nos	Inflammation, Suppurative

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

Experiment Number: C54911

Test Type: Long-Term

Route: Gavage

Species/Strain: Rat/F344

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Test Compound: C.I. Acid orange 3

CAS Number: 6373-74-6

Date Report Requested: 10/26/2014

Time Report Requested: 17:29:07

First Dose M/F: NA / NA

Lab: NA

ANIMAL ID: 1\_014

TRT#: 1

SEX: Female

DAY ON TEST:

DOSE: 750.0 MG/KG

DISP: Moribund Sacrifice

HISTO:

OBSERVATIONS

Adrenal gland	Medulla	Hyperplasia, Focal
Blood vessel	Aorta Nos	Mineralization
	Artery Nos	Mineralization
	Artery Nos	Periarteritis
Bone	Femur	Dysplasia, Fibrous
Eye	Nasolacrimal Duct	Inflammation, Suppurative
Heart		Fibrosis
Intestine Large	Cecum, Colon	Inflammation, Chronic
	Colon	Inflammation, Chronic
	Cecum, Colon	Inflammation, Suppurative
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Salivary gland		Retention Of Content
Stomach	Muscularis	Degeneration, Nos
	Glandular Stomach	Mineralization

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_015

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos Medulla	Cytoplasmic Vacuolization Hyperplasia, Focal
Blood vessel	Aorta Nos Aorta Nos	Inflammation, Chronic Mineralization
Heart		Inflammation, Chronic
Intestine Large	Colon	Inflammation, Suppurative
Kidney	Pelvis	Hyperplasia, Epithelial Inflammation, Chronic Inflammation, Suppurative Nephropathy
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Pituitary gland		Hyperplasia, Nos
Salivary gland		Ectopia
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_016

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

**OBSERVATIONS**

Intestine Large

Rectum

Inflammation, Chronic

Kidney

Rectum

Ulcer, Nos

Inflammation, Chronic

Inflammation, Suppurative

Mineralization

Nephropathy

Liver

Hepatocytes

Cytoplasmic Vacuolization

Pituitary gland

Adenoma, Nos

Thyroid

Cyst, Embryonal Duct

Uterus

Inflammation, Suppurative

Necrosis, Nos

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_017

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel

Artery Nos

Degeneration, Hyaline

Artery Nos

Periarteritis

Heart

Inflammation, Chronic

Kidney

Inflammation, Chronic

Nephropathy

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Pituitary gland

Cyst, Nos

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_018

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Blood vessel

Aorta Nos

Mineralization

Heart

Inflammation, Chronic

Intestine Large

Cecum, Colon

Inflammation, Chronic

Kidney

Pelvis

Hyperplasia, Epithelial

Inflammation, Chronic

Inflammation, Suppurative

Pelvis

Necrosis, Nos

Nephropathy

Nephrosis, Hydro

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_019

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Intestine Large  
Kidney

Colon

Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Liver  
Lymph node  
Thyroid

Hepatocytes  
Mesenteric Lymph Node

Cytoplasmic Vacuolization  
Atrophy, Nos  
Cyst, Embryonal Duct

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_020

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel  
Intestine Large  
Kidney

Aorta Nos  
Colon

Papilla

Liver  
Spleen  
Thyroid

Hepatocytes

Mineralization  
Inflammation, Chronic  
Inflammation, Suppurative  
Necrosis, Nos  
Nephropathy  
Cytoplasmic Vacuolization  
Hemosiderosis  
Cyst, Embryonal Duct

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 1\_021

**TRT#:** 1  
**DOSE:** 750.0 MG/KG

**SEX:** Female  
**DISP:** Moribund Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Blood vessel	Aorta Nos	Mineralization
Bone	Femur	Dysplasia, Fibrous
Heart		Fibrosis
Kidney	Pelvis	Hyperplasia, Epithelial Inflammation, Chronic Inflammation, Suppurative Nephropathy Transitional-Cell Carcinoma
Liver	Bile Duct	Hyperplasia, Nos Leukemia, Mononuclear Cell
Mammary gland		Hyperplasia, Cystic
Parathyroid gland		Hyperplasia, Nos
Stomach	Glandular Stomach	Erosion
Urinary bladder		Inflammation, Suppurative
Vagina		Polyp, Nos

**PRIMARY CAUSE OF DEATH**

-

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_022

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland

Blood vessel

Heart

Kidney

Artery Nos

Pheochromocytoma, Malignant

Periarteritis

Fibrosis

Inflammation, Chronic

Inflammation, Suppurative

Nephropathy

Pigmentation, Nos

Lung

Alveolar Macrophages

Congestion, Nos

Pituitary gland

Cyst, Nos

Hyperplasia, Nos

Stomach

Glandular Stomach

Dysplasia, Epithelial

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_023

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Brain	Cerebrum	Degeneration, Nos
Heart		Fibrosis
Kidney	Pelvis	Hyperplasia, Epithelial Inflammation, Chronic Inflammation, Suppurative Nephropathy
Liver	Bile Duct	Hyperplasia, Nos
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
	Mediastinal Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Infection, Fungal Inflammation, Suppurative

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_024

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel

Artery Nos

Periarteritis

Heart

Fibrosis

Intestine Large

Cecum, Colon

Inflammation, Chronic

Cecum, Colon

Inflammation, Suppurative

Kidney

Inflammation, Chronic

Inflammation, Suppurative

Lymph node

Mesenteric Lymph Node

Nephropathy

Pituitary gland

Atrophy, Nos

Thyroid

Adenoma, Nos

Hyperplasia, C Cell

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_025

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Intestine Large  
Kidney

Cecum, Colon  
Medulla

Inflammation, Chronic  
Hemorrhage  
Inflammation, Chronic  
Inflammation, Suppurative

Medulla

Necrosis, Nos  
Nephropathy

Lymph node  
Stomach  
Uterus

Mesenteric Lymph Node  
Glandular Stomach

Atrophy, Nos  
Ulcer, Nos  
Endometrial Stromal Polyp

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_026

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Brain	Cerebrum	Degeneration, Nos
	Midbrain Nos	Granular-Cell Tumor, Nos
Eye	Retina	Atrophy, Nos
Kidney		Cyst, Nos
		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
		Transitional-Cell Carcinoma
Liver	Bile Duct	Hyperplasia, Nos
Nasal cavity		Inflammation, Suppurative

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_027

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone marrow  
Kidney

Hyperplasia, Reticulum Cell  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Liver  
Mammary gland  
Pancreas  
Thyroid  
Uterus

Bile Duct  
Acinus

Transitional-Cell Carcinoma  
Hyperplasia, Nos  
Hyperplasia, Cystic  
Atrophy, Nos  
C-Cell Adenoma  
Hydrometra

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_028

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Heart		Fibrosis
Kidney		Fibrosis
		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Liver	Bile Duct	Hyperplasia, Nos
Lung		Congestion, Nos
		Edema, Nos
Mammary gland		Hyperplasia, Cystic
Ovary		Cyst, Nos
Pancreas	Acinus	Atrophy, Nos
Uterus		Hemorrhage

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_029

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone	Femur	Dysplasia, Fibrous
Heart		Degeneration, Nos
		Inflammation, Chronic
		Mineralization
Intestine Large	Muscularis, Colon	Degeneration, Nos
	Colon	Inflammation, Chronic
	Colon	Inflammation, Suppurative
Kidney		Inflammation, Suppurative
	Papilla	Necrosis, Nos
		Nephropathy
Lung		Edema, Nos
Spleen		Hemosiderosis
Stomach	Muscularis	Degeneration, Nos
	Glandular Stomach	Mineralization

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 1\_030

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone marrow  
Kidney

Papilla

Fibrosis, Myelo  
Cyst, Nos  
Dysplasia, Epithelial  
Fibrosis  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Liver

Hepatocytes

Cytoplasmic Change, Basophilic  
Inflammation, Chronic  
Congestion, Nos  
Hyperplasia, Cystic  
Hydrometra

Lung  
Mammary gland  
Uterus

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_031

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel  
Intestine Large  
Kidney

Aorta Nos  
Cecum, Colon  
Tubule

Mineralization  
Inflammation, Suppurative  
Cytoplasmic Vacuolization  
Inflammation, Chronic  
Inflammation, Suppurative  
Mineralization

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_032

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

---

**OBSERVATIONS**

Blood vessel  
Intestine Large  
Kidney

Artery Nos  
Colon

Hypertrophy, Nos  
Inflammation, Chronic  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy  
Cytoplasmic Vacuolization  
Atrophy, Nos  
Degeneration, Hyaline  
Polyp, Inflammatory

Liver  
Lymph node  
Pancreas  
Uterus

Hepatocytes  
Mesenteric Lymph Node  
Interstitialium

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_033

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland

Blood vessel

Aorta Nos

Artery Nos

Aorta Nos

Artery Nos

Intestine Large

Colon

Colon

Kidney

Pheochromocytoma

Degeneration, Hyaline

Degeneration, Hyaline

Inflammation, Acute/Chronic

Periarteritis

Inflammation, Chronic

Inflammation, Suppurative

Inflammation, Chronic

Inflammation, Suppurative

Nephropathy

Lymph node

Mandibular Lymph Node

Atrophy, Nos

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_034

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland		Pheochromocytoma
Bone	Femur	Dysplasia, Fibrous
Bone marrow		Atrophy, Nos
Heart		Fibrosis
Kidney		Cyst, Nos
		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
		Pigmentation, Nos
		Transitional-Cell Carcinoma
Lung		Alveolar Macrophages
		Hyperplasia, Alveolar Epithelium
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos
Spleen		Hematopoiesis
Stomach	Muscularis	Degeneration, Nos
Unspecified	Multiple Organs Nos	Mineralization

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_035

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland  
Bone  
Heart  
Intestine Large  
Kidney

Cortex Nos  
Femur  
  
Cecum, Colon  
Pelvis

Cytoplasmic Vacuolization  
Dysplasia, Fibrous  
Fibrosis  
Inflammation, Chronic  
Hyperplasia, Epithelial  
Inflammation, Chronic  
Nephropathy  
Thrombus, Fibrin  
Hyperplasia, Cystic  
Cyst, Nos

Lung  
Mammary gland  
Pituitary gland

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_036

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Heart		Degeneration, Nos Inflammation, Chronic Inflammation, Suppurative
Intestine Large	Colon	Inflammation, Chronic Inflammation, Suppurative
Kidney	Papilla	Necrosis, Nos Nephropathy

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_037

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Blood vessel  
Intestine Large  
Kidney

Artery Nos  
Colon

Periarteritis  
Inflammation, Chronic  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy  
Nephrosis, Hydro  
Ulcer, Nos  
Cyst, Embryonal Duct

Stomach  
Thyroid

Forestomach

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_038

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone	Femur	Dysplasia, Fibrous
Heart		Fibrosis
Intestine Large	Cecum, Colon	Inflammation, Chronic
	Cecum, Colon	Inflammation, Suppurative
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Mammary gland		Pigmentation, Nos
Pancreas	Islets	Hyperplasia, Cystic
Pituitary gland		Islet-Cell Adenoma
		Cyst, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_039

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Heart		Mineralization
Kidney		Inflammation, Suppurative Nephropathy
Lung		Edema, Nos
Stomach	Muscularis	Degeneration, Nos
	Glandular Stomach	Mineralization
Thyroid		Cyst, Embryonal Duct

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_040

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Intestine Large  
Intestine Small  
Kidney

Rectum  
Mesentery Nos

Parasitism  
Necrosis, Fat  
Cyst, Nos  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy  
Pigmentation, Nos  
Transitional-Cell Carcinoma  
Alveolar Macrophages  
Hyperplasia, Cystic  
Keratoacanthoma

Lung  
Mammary gland  
Skin

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 1\_041

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland  
Bone  
Intestine Large

Cortex Nos  
Femur  
Colon  
Colon

Kidney

Cytoplasmic Vacuolization  
Dysplasia, Fibrous  
Inflammation, Chronic  
Inflammation, Suppurative  
Inflammation, Chronic  
Inflammation, Suppurative  
Mineralization  
Nephropathy  
Atrophy, Nos  
Endometrial Stromal Polyp

Lymph node  
Uterus

Mesenteric Lymph Node

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 1\_042

**TRT#:** 1  
**DOSE:** 750.0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Bone	Femur	Dysplasia, Fibrous
Heart		Fibrosis
Intestine Large	Cecum, Colon	Inflammation, Chronic
Kidney		Fibrosis
	Pelvis	Hyperplasia, Epithelial
		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Lung		Alveolar Macrophages
		Thrombus, Fibrin
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Infection, Fungal
		Inflammation, Suppurative
Stomach	Glandular Stomach	Mineralization
	Forestomach	Ulcer, Nos

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_043

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Heart		Degeneration, Nos
Kidney		Inflammation, Suppurative
	Papilla	Necrosis, Nos
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Vacuolization

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_044

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Accidentally Killed

**HISTO:**

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**OBSERVATIONS**

Lung		Congestion, Nos
Lymph node	Mesenteric Lymph Node	Hyperplasia, Lymphoid
Unspecified	Mediastinum Nos	Foreign Body, Nos
Uterus		Hydrometra

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 1\_045

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone marrow		Megakaryocytosis
Eye	Retina	Atrophy, Nos
Intestine Large	Cecum, Colon	Edema, Nos
	Cecum, Colon	Inflammation, Chronic
	Cecum, Colon	Inflammation, Suppurative
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
	Papilla	Necrosis, Nos
		Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Bile Duct	Hyperplasia, Nos
		Necrosis, Focal
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
	Renal Lymph Node	Lymphangiectasis
Mammary gland		Hyperplasia, Cystic
Ovary		Cyst, Nos
Pituitary gland		Hyperplasia, Nos
Thyroid		Inflammation, Pyogranulomatous
Trachea		Inflammation, Pyogranulomatous
		Necrosis, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_046

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Kidney

Inflammation, Suppurative

Papilla

Necrosis, Nos

Thyroid

Nephropathy

Cyst, Embryonal Duct

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_047

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Intestine Large  
Kidney

Cecum, Colon  
Pelvis

Inflammation, Chronic  
Hyperplasia, Epithelial  
Inflammation, Chronic  
Inflammation, Suppurative  
Nephropathy

Lymph node  
Urinary bladder

Mesenteric Lymph Node

Lymphangiectasis  
Hyperplasia, Epithelial

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_048

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Natural Death

**HISTO:**

---

**OBSERVATIONS**

Clitoral gland  
Intestine Small  
Kidney

Mesentery Nos

Hyperplasia, Nos  
Necrosis, Fat  
Inflammation, Chronic  
Inflammation, Suppurative  
Mineralization

Skin  
Uterus

Perineum

Nephropathy  
Papilloma, Nos  
Hydrometra

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_049

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland  
Kidney

Medulla

Hyperplasia, Diffuse  
Inflammation, Suppurative

Papilla

Necrosis, Nos

Lymph node  
Spleen

Mesenteric Lymph Node

Nephropathy

Atrophy, Nos

Hemosiderosis

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 1\_050

**TRT#:** 1

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 750.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Adrenal gland

Kidney

Papilla

Pheochromocytoma

Inflammation, Suppurative

Necrosis, Nos

Nephropathy

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_001

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Natural Death

**HISTO:**

---

**OBSERVATIONS**

Kidney

Nephropathy

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Bile Duct

Hyperplasia, Nos

Mammary gland

Hyperplasia, Cystic

Pituitary gland

Adenoma, Nos

Skin

Basal-Cell Tumor

Uterus

Endometrial Stromal Polyp

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_002

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Adrenal gland

Cortex Nos

Cytoplasmic Vacuolization

Heart

Fibrosis

Kidney

Nephropathy

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Mammary gland

Fibroadenoma

Pituitary gland

Hyperplasia, Cystic

Spleen

Adenoma, Nos

Thyroid

Hematopoiesis

Cyst, Embryonal Duct

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_003

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Brain	Cerebrum	Degeneration, Nos
Clitoral gland		Inflammation, Granulomatous
Eye	Retina	Atrophy, Nos
		Cataract
Heart		Inflammation, Chronic
Intestine Large	Colon	Parasitism
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Angiectasis

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_004

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Kidney	Pelvis	Hyperplasia, Epithelial Inflammation, Chronic Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Ovary		Cyst, Parovarian
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_005

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Moribund Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Blood vessel Clitoral gland	Artery Nos	Necrosis, Fibrinoid Hyperplasia, Nos Inflammation, Suppurative Retention Of Content
Heart Kidney	Pelvis	Fibrosis Hyperplasia, Epithelial Inflammation, Suppurative Nephropathy
Liver	Hepatocytes Bile Duct	Atrophy, Focal Hyperplasia, Nos
Lymph node Nasal cavity	Mesenteric Lymph Node	Atrophy, Nos Infection, Fungal Inflammation, Suppurative
Stomach Unspecified	Glandular Stomach Multiple Organs Nos	Ulcer, Nos Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_006

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Blood vessel	Pulmonary Artery Nos	Mineralization
Brain	Cerebrum	Degeneration, Nos
Clitoral gland		Inflammation, Granulomatous
Eye	Retina	Atrophy, Nos
		Cataract
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney	Papilla	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
	Mandibular Lymph Node	Lymphangiectasis
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Cyst, Nos

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_007

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Blood vessel	Pulmonary Artery Nos	Mineralization
Clitoral gland		Retention Of Content
Eye	Retina	Atrophy, Nos
		Cataract
Kidney		Inflammation, Chronic
	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
		Hyperplasia, Alveolar Epithelium
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos
Salivary gland		Atrophy, Nos
Thyroid		C-Cell Adenoma
Uterus		Endometrial Stromal Polyp
	Endometrium	Hyperplasia, Cystic

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_008

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Heart		Fibrosis
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Bile Duct	Hyperplasia, Nos
	Kupffer Cell	Pigmentation, Nos
Lung		Inflammation, Suppurative
Pancreas	Acinus	Atrophy, Nos
	Islets	Islet-Cell Adenoma
Pituitary gland		Adenoma, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_009

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cyst, Hemorrhagic
Eye	Retina	Atrophy, Nos Cataract
Kidney	Pelvis	Inflammation, Chronic Mineralization Nephropathy Nephrosis, Hydro
Liver	Hepatocytes Bile Duct	Cytoplasmic Change, Basophilic Hyperplasia, Nos
Lymph node	Mesenteric Lymph Node Mediastinal Lymph Node Mediastinal Lymph Node	Atrophy, Nos Erythrophagocytosis Pigmentation, Nos
Mammary gland		Fibroadenoma
Pituitary gland		Adenoma, Nos
Skin		Basal-Cell Tumor
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

Experiment Number: C54911

Test Type: Long-Term

Route: Gavage

Species/Strain: Rat/F344

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Test Compound: C.I. Acid orange 3

CAS Number: 6373-74-6

Date Report Requested: 10/26/2014

Time Report Requested: 17:29:07

First Dose M/F: NA / NA

Lab: NA

ANIMAL ID: 2\_010

TRT#: 2

SEX: Female

DAY ON TEST:

DOSE: 375.0 MG/KG

DISP: Terminal Sacrifice

HISTO:

OBSERVATIONS

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Eye	Retina	Atrophy, Nos Cataract
Heart		Fibrosis
Kidney		Angiectasis Inflammation, Chronic
	Pelvis	Mineralization Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos Inflammation, Chronic Neoplastic Nodule
Lung		Alveolar Macrophages
Lymph node	Mandibular Lymph Node	Plasmacytosis
Mammary gland		Fibroadenoma
Nasal cavity		Infection, Fungal Inflammation, Suppurative
Pituitary gland		Angiectasis Cyst, Nos
Skin		Basal-Cell Tumor
Spleen		Fibrosis
Thyroid		Hyperplasia, C Cell
Uterus		Inflammation, Suppurative

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_011

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland		Pheochromocytoma
Eye	Retina	Atrophy, Nos Cataract
Kidney		Inflammation, Suppurative Nephropathy
Liver		Hematopoiesis
Lymph node	Bile Duct	Hyperplasia, Nos
Mammary gland	Mandibular Lymph Node	Lymphangiectasis
Pancreas	Acinus	Hyperplasia, Cystic Atrophy, Nos
Pituitary gland		Adenoma, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_012

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland  
Clitoral gland

Hematopoiesis  
Hyperplasia, Nos  
Inflammation, Suppurative  
Retention Of Content

Eye

Retina

Atrophy, Nos  
Cataract

Intestine Small  
Kidney

Mesentery Nos  
Pelvis

Necrosis, Fat  
Mineralization  
Nephropathy  
Nephrosis, Hydro

Liver

Bile Duct  
Hepatocytes  
Mesenteric Lymph Node

Hematopoiesis  
Hyperplasia, Nos  
Necrosis, Focal

Lymph node  
Mammary gland

Atrophy, Nos  
Fibroadenoma  
Hyperplasia, Cystic

Spleen  
Stomach

Glandular Stomach  
Glandular Stomach  
Muscularis

Hematopoiesis  
Cyst, Nos  
Mineralization

Urinary bladder  
Uterus

Serosa

Mineralization  
Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_013

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Heart		Inflammation, Chronic
Kidney		Inflammation, Chronic Inflammation, Suppurative
	Pelvis	Mineralization
Liver	Hepatocytes	Nephropathy Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Pituitary gland		Cyst, Nos
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_014

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Kidney	Pelvis	Mineralization Nephropathy
Liver	Hepatocytes Bile Duct	Cytoplasmic Change, Basophilic Hyperplasia, Nos
Lung		Alveolar Macrophages Cholesterol Deposit Inflammation, Granulomatous
Mammary gland		Hyperplasia, Cystic
Urinary bladder		Inflammation, Chronic
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_015

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Adrenal gland

Cortex Nos

Cytoplasmic Vacuolization

Eye

Retina

Atrophy, Nos

Cataract

Kidney

Inflammation, Chronic

Inflammation, Suppurative

Pelvis

Mineralization

Nephropathy

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Mammary gland

Hyperplasia, Cystic

Pituitary gland

Adenoma, Nos

Skin

Papilloma, Nos

Thyroid

C-Cell Adenoma

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_016

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Intestine Large	Colon	Parasitism
Kidney		Nephropathy
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Skin		Neurofibrosarcoma
Spleen		Hematopoiesis
Uterus		Endometrial Stromal Polyp

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_017

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland  
Blood vessel  
Eye

Cortex Nos  
Pulmonary Artery Nos  
Retina

Angiectasis  
Mineralization  
Atrophy, Nos  
Cataract

Kidney  
Liver

Hepatocytes  
Bile Duct

Inflammation, Chronic  
Cytoplasmic Change, Basophilic  
Hyperplasia, Nos  
Inflammation, Chronic

Lung  
Mammary gland  
Uterus

Endometrium

Alveolar Macrophages  
Hyperplasia, Cystic  
Hyperplasia, Cystic

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_018

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Blood vessel	Pulmonary Artery Nos	Mineralization
Eye	Retina	Atrophy, Nos
		Cataract
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
Lymph node	Mediastinal Lymph Node	Erythrophagocytosis
	Mediastinal Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_019

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
	Medulla	Cytoplasmic Vacuolization
Blood vessel	Artery Nos	Necrosis, Fibrinoid
Intestine Large	Cecum, Colon	Inflammation, Chronic
	Cecum, Colon	Inflammation, Suppurative
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Vacuolization
Salivary gland		Retention Of Content
Skin		Fibroma
Stomach	Glandular Stomach	Ulcer, Nos

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_020

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Heart		Inflammation, Chronic
Kidney		Inflammation, Chronic
	Pelvis	Mineralization
Liver	Hepatocytes	Nephropathy
	Bile Duct	Cytoplasmic Change, Basophilic
	Mesenteric Lymph Node	Hyperplasia, Nos
Lymph node		Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_021

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Blood vessel	Pulmonary Artery Nos	Mineralization
Bone marrow		Hyperplasia, Reticulum Cell
Clitoral gland		Inflammation, Suppurative
		Retention Of Content
Eye	Retina	Atrophy, Nos
		Cataract
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Cyst, Nos

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_022

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Change, Basophilic
Brain	Cerebrum	Hemorrhage
Eye	Retina	Atrophy, Nos
		Cataract
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Bile Duct	Hyperplasia, Nos
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Fibroadenoma
Pituitary gland		Angiectasis
		Cyst, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_023

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Heart		Fibrosis
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lymph node	Mesenteric Lymph Node	Mastocytosis
	Mediastinal Lymph Node	Pigmentation, Nos
Pituitary gland		Angiectasis
Skin		Fibroma

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_024

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Blood vessel  
Kidney

Artery Nos

Periarteritis  
Mineralization  
Nephropathy  
Hyperplasia, Cystic  
Adenoma, Nos

Mammary gland  
Pituitary gland

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_025

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Kidney	Pelvis	Mineralization Nephropathy Nephrosis, Hydro
Liver	Hepatocytes	Cytoplasmic Change, Basophilic Inflammation, Chronic
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Infection, Fungal Inflammation, Suppurative
Pituitary gland		Adenoma, Nos Angiectasis
Thyroid		C-Cell Adenoma
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_026

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Pituitary gland

Skin

Spleen

Thyroid

Adenoma, Nos

Fibroma

Hematopoiesis

C-Cell Adenoma

Cyst, Embryonal Duct

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_027

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Hyperplasia, Focal
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney		Inflammation, Chronic
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
		Hyperplasia, Alveolar Epithelium
Lymph node	Mesenteric Lymph Node	Mastocytosis
	Mediastinal Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
	Acinus	Inflammation, Chronic
Pituitary gland		Cyst, Nos
Thyroid		Hyperplasia, C Cell
Uterus		Adenoma, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_028

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Kidney

Nephropathy

Liver

Hepatocytes

Atrophy, Focal

Hepatocytes

Cytoplasmic Change, Basophilic

Bile Duct

Hyperplasia, Nos

Lymph node

Mediastinal Lymph Node

Erythrophagocytosis

Pituitary gland

Adenoma, Nos

Cyst, Nos

Intermedia

Hyperplasia, Nos

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_029

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland

Cortex Nos

Congenital Malformation, Nos

Blood vessel

Pulmonary Artery Nos

Cytoplasmic Vacuolization

Kidney

Pelvis

Mineralization

Inflammation, Chronic

Liver

Hepatocytes

Mineralization

Nephropathy

Angiectasis

Atrophy, Focal

Lung

Inflammation, Chronic

Mammary gland

Alveolar Macrophages

Ovary

Hyperplasia, Cystic

Pituitary gland

Cyst, Nos

Adenoma, Nos

Uterus

Endometrium

Angiectasis

Cyst, Nos

Hyperplasia, Cystic

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_030

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Natural Death

**HISTO:**

---

**OBSERVATIONS**

Heart

Kidney

Lung

Unspecified

Multiple Organs Nos

Fibrosis

Inflammation, Suppurative

Nephropathy

Edema, Nos

Leukemia, Mononuclear Cell

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_031

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Esophagus

Heart

Pituitary gland

Retention Of Content

Fibrosis

Angiectasis

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_032

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Bone marrow

Congestion, Nos

Heart

Pigmentation, Nos

Kidney

Papilla

Fibrosis

Pelvis

Mineralization

Liver

Hepatocytes

Mineralization

Lung

Bile Duct

Nephropathy

Pituitary gland

Nephrosis, Hydro

Unspecified

Multiple Organs Nos

Cytoplasmic Change, Basophilic

Urinary bladder

Hyperplasia, Nos

Alveolar Macrophages

Angiectasis

Cyst, Nos

Leukemia, Mononuclear Cell

Inflammation, Chronic

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**PRIMARY CAUSE OF DEATH**

-

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**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_033

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Degeneration, Lipoid Pheochromocytoma
Blood vessel	Artery Nos Artery Nos	Hypertrophy, Nos Mineralization
Bone marrow		Hyperplasia, Nos
Kidney		Mineralization Nephropathy
Liver	Hepatocytes	Necrosis, Central
Lung		Edema, Nos Hyperplasia, Alveolar Epithelium Inflammation, Suppurative
Lymph node	Mandibular Lymph Node	Plasmacytosis
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Foreign Material, Nos Infection, Fungal Inflammation, Suppurative
Pituitary gland		Adenoma, Nos
Stomach	Glandular Stomach	Erosion
Trachea		Metaplasia, Squamous

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_034

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Bone marrow		Hyperplasia, Reticulum Cell
Clitoral gland		Inflammation, Chronic
Heart		Fibrosis
Kidney		Inflammation, Chronic
		Inflammation, Suppurative
		Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Lymph node	Mediastinal Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Angiectasis
		Cyst, Nos
		Hyperplasia, Nos
Thyroid		C-Cell Adenoma

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_035

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Kidney

Papilla

Mineralization

Pelvis

Mineralization

Liver

Bile Duct

Nephropathy

Hyperplasia, Nos

Mammary gland

Neoplastic Nodule

Pituitary gland

Hyperplasia, Cystic

Stomach

Angiectasis

Unspecified

Glandular Stomach

Cyst, Nos

Multiple Organs Nos

Leukemia, Mononuclear Cell

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_036

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cyst, Hemorrhagic
Heart		Inflammation, Chronic
Kidney		Inflammation, Chronic
	Papilla	Inflammation, Suppurative
		Mineralization
Liver	Hepatocytes	Nephropathy
	Bile Duct	Cytoplasmic Change, Basophilic
Pituitary gland		Hyperplasia, Nos
		Cyst, Nos
Uterus		Hyperplasia, Nos
		Cyst, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_037

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Heart		Degeneration, Nos
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Mammary gland		Hyperplasia, Cystic
Thyroid	Follicle	Dilatation, Nos
Uterus		Adenoma, Nos
	Endometrium	Hyperplasia, Cystic

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**PRIMARY CAUSE OF DEATH**

-

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**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_038

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Clitoral gland		Adenoma, Nos
Heart		Fibrosis
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pituitary gland		Cyst, Nos
Skin		Acanthosis
		Hyperkeratosis
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_039

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos
Kidney	Pelvis	Mineralization Nephropathy
Liver	Hepatocytes	Atrophy, Focal
Lung	Bile Duct	Hyperplasia, Nos Alveolar Macrophages Inflammation, Suppurative
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pharynx		Inflammation, Suppurative
Pituitary gland		Adenoma, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_040

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Adrenal gland  
Heart  
Kidney

Cortex Nos

Hyperplasia, Focal  
Fibrosis  
Inflammation, Chronic

Liver

Pelvis  
Hepatocytes  
Hepatocytes  
Bile Duct

Mineralization  
Atrophy, Focal  
Cytoplasmic Change, Basophilic  
Hyperplasia, Nos  
Alveolar Macrophages  
Fibroadenoma  
Hyperplasia, Nos  
Inflammation, Chronic

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Lung  
Mammary gland

Urinary bladder

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_041

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Intestine Small

Mesentery Nos

Mineralization

Kidney

Mesentery Nos

Necrosis, Fat

Liver

Hepatocytes

Nephropathy

Lymph node

Bile Duct

Atrophy, Focal

Mammary gland

Mandibular Lymph Node

Hyperplasia, Nos

Pituitary gland

Mediastinal Lymph Node

Hemorrhage

Unspecified

Multiple Organs Nos

Lymphangiectasis

Hyperplasia, Cystic

Cyst, Nos

Leukemia, Mononuclear Cell

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_042

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Intestine Large	Cecum, Colon	Parasitism
	Rectum	Parasitism
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Mammary gland		Hyperplasia, Nos
Pituitary gland		Adenoma, Nos
Salivary gland		Atrophy, Nos
Thyroid		Hyperplasia, Follicular Cell
Uterus		Endometrial Stromal Polyp

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_043

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Clitoral gland

Kidney

Adenoma, Nos

Inflammation, Chronic

Nephropathy

Nephrosis, Hydro

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Mammary gland

Hyperplasia, Cystic

Nasal cavity

Infection, Fungal

Inflammation, Suppurative

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_044

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Heart		Fibrosis
Intestine Large	Rectum	Parasitism
Kidney		Inflammation, Chronic
	Papilla	Mineralization
	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Congestion, Nos
Mammary gland		Fibrosis
		Hyperplasia, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp
	Endometrium	Hyperplasia, Epithelial

PRIMARY CAUSE OF DEATH

-

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_045

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Intestine Large  
Liver  
Lung

Colon  
Hepatocytes

Parasitism  
Cytoplasmic Change, Basophilic  
Alveolar Macrophages  
Congestion, Nos  
Edema, Nos  
Hemorrhage  
Hyperplasia, Cystic  
C-Cell Adenoma

Lymph node  
Mammary gland  
Thyroid

Mesenteric Lymph Node

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**PRIMARY CAUSE OF DEATH**

-

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**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 2\_046

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Kidney

Pelvis

Mineralization

Nephropathy

Nephrosis, Hydro

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Bile Duct

Hyperplasia, Nos

Mammary gland

Fibroadenoma

Hyperplasia, Cystic

Pancreas

Acinus

Inflammation, Chronic

Pituitary gland

Adenoma, Nos

Thyroid

Hyperplasia, C Cell

Urinary bladder

Inflammation, Chronic

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 2\_047

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos
Kidney		Nephropathy
Liver		Hyperplasia, Nodular
	Bile Duct	Hyperplasia, Nos
	Kupffer Cell	Pigmentation, Nos
Lung		Hyperplasia, Alveolar Epithelium
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Angiectasis
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_048

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Heart		Fibrosis
Kidney		Nephropathy Nephrosis, Hydro
Liver	Hepatocytes	Atrophy, Focal Hepatocellular Carcinoma
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages Inflammation, Granulomatous
Mammary gland		Fibroadenoma Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos Cyst, Nos
Spleen		Fibrosis
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 2\_049

**TRT#:** 2  
**DOSE:** 375.0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Kidney		Inflammation, Chronic Inflammation, Suppurative Nephropathy Nephrosis, Hydro
Liver	Hepatocytes Bile Duct	Cytoplasmic Change, Basophilic Hyperplasia, Nos Carcinoma, Nos Hyperplasia, Cystic
Mammary gland		Inflammation, Suppurative
Nasal cavity		Atrophy, Nos
Pancreas	Acinus	Adenoma, Nos
Pituitary gland		C-Cell Adenoma
Thyroid		Endometrial Stromal Polyp
Uterus		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 2\_050

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 375.0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Intestine Small  
Kidney

Mesentery Nos  
Pelvis

Lipoma  
Mineralization  
Nephropathy

Liver

Hepatocytes  
Bile Duct

Cytoplasmic Change, Basophilic  
Hyperplasia, Nos

Mammary gland

Pancreas

Pituitary gland

Thyroid

Acinus

Hyperplasia, Cystic  
Inflammation, Chronic  
Cyst, Nos  
C-Cell Adenoma

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_001

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos Cortex Nos	Cytoplasmic Vacuolization Inflammation, Granulomatous
Bone marrow		Hyperplasia, Reticulum Cell
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney	Pelvis	Mineralization Nephrosis, Hydro
Liver	Hepatocytes	Cytoplasmic Change, Basophilic Inflammation, Granulomatous
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node Mesenteric Lymph Node	Atrophy, Nos Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Ovary		Inflammation, Granulomatous Necrosis, Nos
Pituitary gland		Adenoma, Nos
Salivary gland		Adenoma, Nos
Thymus		Cyst, Nos
Thyroid		Hyperplasia, C Cell
Uterus		Hydrometra

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_002

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Clitoral gland		Carcinoma, Nos
Intestine Large	Cecum, Colon	Parasitism
Kidney	Pelvis	Mineralization
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
		Inflammation, Chronic
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
	Islets	Islet-Cell Adenoma
Pituitary gland		Adenoma, Nos
Spleen		Hematopoiesis

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_003

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Bone	Femur	Hyperostosis
Heart		Fibrosis
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
		Inflammation, Chronic
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos
Spleen		Hematopoiesis
Stomach	Glandular Stomach	Dysplasia, Epithelial
Thyroid		C-Cell Adenoma
Vagina		Polyp, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_004

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland		Pheochromocytoma
Bone marrow		Hyperplasia, Reticulum Cell
Heart		Fibrosis
Kidney		Nephropathy
		Nephrosis, Hydro
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
Lymph node	Mandibular Lymph Node	Lymphangiectasis
	Mediastinal Lymph Node	Pigmentation, Nos
	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Angiectasis
		Cyst, Nos
Skin		Inflammation, Suppurative
Thyroid		Cyst, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_005

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization Pheochromocytoma
Eye	Retina	Atrophy, Nos
Kidney		Nephropathy
Liver	Hepatocytes	Atrophy, Focal Hyperplasia, Nodular
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages Hemorrhage
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Spleen		Necrosis, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_006

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Medulla	Hyperplasia, Focal
	Cortex Nos	Hypertrophy, Nos
Blood vessel	Pulmonary Artery Nos	Mineralization
Heart		Fibrosis
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
	Hepatocytes	Cytoplasmic Vacuolization
		Inflammation, Chronic
Lymph node	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Thyroid		C-Cell Adenoma
Uterus		Hydrometra

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_007

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Heart		Fibrosis
Intestine Large	Rectum	Parasitism
Kidney	Pelvis	Mineralization
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Nasal cavity		Infection, Fungal
		Inflammation, Suppurative
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell
Urinary bladder	Serosa	Mineralization
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_008

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Heart		Fibrosis
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
		Inflammation, Chronic
		Inflammation, Granulomatous
Lymph node	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_009

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Heart		Fibrosis
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
	Kupffer Cell	Pigmentation, Nos
Lung		Alveolar Macrophages
Lymph node	Mandibular Lymph Node	Hyperplasia, Lymphoid
	Mesenteric Lymph Node	Hyperplasia, Lymphoid
	Mediastinal Lymph Node	Pigmentation, Nos
	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Nasal cavity		Inflammation, Suppurative
Pituitary gland		Cyst, Nos
Spleen		Hemosiderosis
Stomach	Muscularis	Mineralization
Thyroid		Hyperplasia, C Cell
Uterus		Adenoma, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_010

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Heart		Fibrosis
Kidney	Pelvis	Mineralization
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Thymus		Squamous Cell Carcinoma
Thyroid		Hyperplasia, C Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_011

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Heart		Degeneration, Nos Inflammation, Chronic
Kidney	Pelvis	Mineralization
Liver	Bile Duct	Hyperplasia, Nos
	Kupffer Cell	Pigmentation, Nos
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pituitary gland		Cyst, Nos
		Hyperplasia, Nos
Spleen		Fibrosis
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

**PRIMARY CAUSE OF DEATH**

-

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_012

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland		Cortical Adenoma
	Medulla	Hyperplasia, Nos
Intestine Large	Colon	Parasitism
Kidney	Pelvis	Mineralization
		Nephrosis, Hydro
Liver	Bile Duct	Hyperplasia, Nos
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Lymph node	Celiac Lymph Node	Hemorrhage
	Mediastinal Lymph Node	Hemorrhage
	Celiac Lymph Node	Pigmentation, Nos
Mammary gland		Hyperplasia, Cystic
Nasal cavity		Inflammation, Suppurative
Pituitary gland		Adenoma, Nos
Stomach	Muscularis	Mineralization

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_013

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Bone marrow  
Kidney  
Liver  
Lung  
Lymph node  
Mammary gland

Pelvis  
Hepatocytes  
  
Mesenteric Lymph Node

Hyperplasia, Reticulum Cell  
Mineralization  
Cytoplasmic Change, Basophilic  
Alveolar Macrophages  
Atrophy, Nos  
Fibroadenoma  
Hyperplasia, Cystic  
Adenoma, Nos  
Fibroma  
Hyperplasia, C Cell  
Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_014

**TRT#:** 3

**DOSE:** 0

**SEX:** Female

**DISP:** Terminal Sacrifice

**DAY ON TEST:**

**HISTO:**

**OBSERVATIONS**

Clitoral gland		Inflammation, Suppurative
Heart		Fibrosis
Kidney	Pelvis	Mineralization
		Nephropathy
Liver		Angiectasis
	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_015

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Heart		Inflammation, Chronic
Liver	Hepatocytes	Atrophy, Focal
	Bile Duct	Hyperplasia, Nos
Mammary gland		Hyperplasia, Cystic
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_016

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Kidney		Cyst, Nos Inflammation, Chronic
	Pelvis	Mineralization Nephropathy
Liver	Hepatocytes Hepatocytes Bile Duct	Atrophy, Focal Cytoplasmic Change, Basophilic Hyperplasia, Nos
Mammary gland		Fibroadenoma Hyperplasia, Cystic
Pancreas	Acinus Islets	Atrophy, Nos Hyperplasia, Nos
Pituitary gland		Adenoma, Nos
Stomach	Muscularis	Mineralization
Thyroid		Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_017

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Intestine Small

Liver

Lung

Mammary gland

Pituitary gland

Thyroid

Mesentery Nos

Hepatocytes

Bile Duct

Necrosis, Fat

Atrophy, Focal

Hyperplasia, Nos

Alveolar Macrophages

Hyperplasia, Cystic

Angiectasis

Cyst, Nos

Hyperplasia, Nos

Hyperplasia, C Cell

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_018

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland		Cortical Adenoma
	Medulla	Hyperplasia, Focal
Blood vessel	Pulmonary Artery Nos	Mineralization
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Hemorrhage
	Mandibular Lymph Node	Lymphangiectasis
Mammary gland		Hyperplasia, Cystic
Ovary		Cyst, Nos
Pituitary gland		Angiectasis
		Cyst, Nos
Skin		Acanthosis
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_019

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Intestine Large  
Kidney

Rectum  
Pelvis

Parasitism  
Mineralization

Liver

Bile Duct

Nephropathy  
Hyperplasia, Nos  
Inflammation, Granulomatous

Lymph node

Mesenteric Lymph Node  
Mediastinal Lymph Node  
Mesenteric Lymph Node

Atrophy, Nos  
Pigmentation, Nos  
Pigmentation, Nos

Mammary gland  
Pituitary gland

Hyperplasia, Cystic  
Cyst, Nos

Stomach  
Thyroid

Muscularis

Hyperplasia, Nos  
Mineralization  
C-Cell Adenoma

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_020

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Medulla	Hyperplasia, Nos
Kidney	Pelvis	Mineralization
		Nephropathy
Liver		Angiectasis
	Bile Duct	Hyperplasia, Nos
	Kupffer Cell	Pigmentation, Nos
Lung		Alveolar Macrophages
		Hyperplasia, Alveolar Epithelium
Lymph node	Mandibular Lymph Node	Histiocytosis
	Mesenteric Lymph Node	Pigmentation, Nos
	Mandibular Lymph Node	Plasmacytosis
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_021

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Natural Death

**HISTO:**

**OBSERVATIONS**

Clitoral gland		Hyperplasia, Nos Inflammation, Chronic
Kidney		Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Congestion, Nos
Lymph node	Mesenteric Lymph Node	Pigmentation, Nos
Mammary gland		Carcinoma, Nos Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos
Stomach	Forestomach	Mineralization
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_022

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Bone marrow		Hyperplasia, Reticulum Cell
Brain	Cerebrum	Degeneration, Nos
	Thalamus	Degeneration, Nos
Clitoral gland		Adenoma, Nos
		Inflammation, Granulomatous
Heart		Inflammation, Chronic
Kidney		Nephrosis, Hydro
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
Lung		Alveolar Macrophages
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell
Uterus		Endometrial Stromal Polyp

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_023

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland

Heart

Intestine Small

Kidney

Mesentery Nos

Liver

Hepatocytes

Bile Duct

Lymph node

Mesenteric Lymph Node

Mammary gland

Thyroid

Pheochromocytoma

Fibrosis

Necrosis, Fat

Inflammation, Chronic

Nephropathy

Cytoplasmic Change, Basophilic

Hyperplasia, Nos

Inflammation, Granulomatous

Pigmentation, Nos

Hyperplasia, Cystic

C-Cell Adenoma

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_024

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Intestine Large

Colon

Parasitism

Kidney

Nephropathy

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Inflammation, Granulomatous

Lung

Alveolar Macrophages

Lymph node

Mesenteric Lymph Node

Pigmentation, Nos

Pancreas

Acinus

Atrophy, Nos

Pituitary gland

Adenoma, Nos

Cyst, Nos

Hyperplasia, Nos

Skin

Fibroma

Thyroid

Hyperplasia, C Cell

Uterus

Inflammation, Suppurative

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_025

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Intestine Large

Cecum, Colon

Parasitism

Kidney

Colon

Parasitism

Liver

Hepatocytes

Nephropathy

Lung

Cytoplasmic Change, Basophilic

Mammary gland

Inflammation, Granulomatous

Alveolar Macrophages

Ovary

Carcinoma, Nos

Pituitary gland

Hyperplasia, Cystic

Thyroid

Cyst, Nos

Uterus

Adenoma, Nos

Hyperplasia, C Cell

Endometrial Stromal Polyp

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_026

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Spleen

Lymphangiectasis

Thyroid

Hematopoiesis

Urinary bladder

Cyst, Embryonal Duct

Hyperplasia, C Cell

Uterus

Endometrial Stromal Sarcoma, Invasive

Hyperplasia, Epithelial

Endometrial Stromal Sarcoma

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_027

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland  
Intestine Large  
Liver

Cecum, Colon  
Hepatocytes  
Bile Duct

Pheochromocytoma  
Parasitism  
Atrophy, Focal  
Hyperplasia, Nos  
Neoplastic Nodule

Lung  
Lymph node

Mesenteric Lymph Node  
Mediastinal Lymph Node

Hemorrhage  
Atrophy, Nos  
Pigmentation, Nos

Mammary gland

Fibroadenoma  
Hyperplasia, Cystic

Thyroid  
Unspecified

Multiple Organs Nos

C-Cell Adenoma  
Leukemia, Mononuclear Cell  
Hydrometra

Uterus

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_028

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland  
Intestine Large  
Kidney

Cortex Nos  
Rectum  
Pelvis

Cytoplasmic Vacuolization  
Parasitism  
Mineralization  
Nephropathy

Liver

Hepatocytes  
Bile Duct

Cytoplasmic Change, Basophilic  
Hyperplasia, Nos  
Fibroadenoma  
Hyperplasia, Cystic

Mammary gland

Pancreas  
Pituitary gland  
Thyroid

Acinus

Atrophy, Nos  
Adenoma, Nos  
C-Cell Adenoma  
Hyperplasia, C Cell

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_029

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Inflammation, Chronic
Kidney	Pelvis	Mineralization
Liver	Hepatocytes	Cytoplasmic Change, Basophilic Inflammation, Granulomatous
Mammary gland		Fibroadenoma

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_030

**TRT#:** 3

**DOSE:** 0

**SEX:** Female

**DISP:** Natural Death

**DAY ON TEST:**

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Intestine Large	Colon	Parasitism
Liver		Inflammation, Granulomatous
Lung		Congestion, Nos
Pituitary gland		Adenoma, Nos
Spleen		Hemosiderosis

---

**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_031

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland

Bone marrow

Kidney

Liver

Pelvis

Bile Duct

Pheochromocytoma

Hyperplasia, Reticulum Cell

Mineralization

Hyperplasia, Nos

Inflammation, Granulomatous

Alveolar Macrophages

Hyperplasia, Cystic

Adenoma, Nos

Fibrosis

Hemosiderosis

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_032

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Moribund Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cyst, Hemorrhagic
	Cortex Nos	Cytoplasmic Vacuolization
Intestine Large	Colon	Inflammation, Chronic
Kidney		Nephropathy
		Nephrosis, Hydro
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Nos
	Hepatocytes	Necrosis, Focal
Lymph node	Pelvic Lymph Node	Adenocarcinoma, Nos, Invasive
	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Cyst, Nos
Unspecified	Multiple Organs Nos	Hematopoiesis
Uterus		Adenocarcinoma, Nos
		Hydrometra

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_033

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Adrenal gland

Intestine Small

Lung

Mammary gland

Pituitary gland

Thyroid

Mesentery Nos

Cortical Adenoma

Necrosis, Fat

Alveolar Macrophages

Hyperplasia, Cystic

Adenoma, Nos

Hyperplasia, C Cell

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_034

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Blood vessel	Pulmonary Artery Nos	Mineralization
Kidney		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
		Fibrosis
		Inflammation, Granulomatous
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911  
**Test Type:** Long-Term  
**Route:** Gavage  
**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** C.I. Acid orange 3  
**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014  
**Time Report Requested:** 17:29:07  
**First Dose M/F:** NA / NA  
**Lab:** NA

**ANIMAL ID:** 3\_035

**TRT#:** 3  
**DOSE:** 0

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:**  
**HISTO:**

**OBSERVATIONS**

Adrenal gland	Cortex Nos Cortex Nos	Cyst, Hemorrhagic Hyperplasia, Focal
Heart		Inflammation, Chronic
Kidney		Nephropathy
Liver	Hepatocytes Bile Duct	Cytoplasmic Change, Basophilic Hyperplasia, Nos Inflammation, Granulomatous
Lung		Alveolar Macrophages Edema, Nos Inflammation, Suppurative
Mammary gland		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Skin		Inflammation, Chronic
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell
Uterus		Adenoma, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_036

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Blood vessel  
Bone marrow  
Clitoral gland  
Intestine Large  
Liver

Pulmonary Artery Nos

Cecum, Colon

Hepatocytes

Lung  
Mammary gland

Thyroid  
Uterus

Mineralization  
Hyperplasia, Reticulum Cell  
Inflammation, Chronic  
Parasitism  
Cytoplasmic Change, Basophilic  
Inflammation, Granulomatous  
Alveolar Macrophages  
Fibroadenoma  
Hyperplasia, Cystic  
Hyperplasia, C Cell  
Hydrometra

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_037

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Kidney

Nephropathy

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Bile Duct

Hyperplasia, Nos

Lung

Alveolar Macrophages

Mammary gland

Hyperplasia, Cystic

Ovary

Cyst, Nos

Pituitary gland

Cyst, Nos

Hyperplasia, Nos

Thyroid

C-Cell Adenoma

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_038

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Intestine Large

Rectum

Parasitism

Kidney

Nephropathy

Liver

Hepatocytes

Atrophy, Focal

Hepatocytes

Cytoplasmic Change, Basophilic

Lung

Alveolar Macrophages

Mammary gland

Fibroadenoma

Thyroid

C-Cell Adenoma

Unspecified

Multiple Organs Nos

Leukemia, Mononuclear Cell

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_039

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Adrenal gland

Cortex Nos

Cytoplasmic Vacuolization

Clitoral gland

Medulla

Hyperplasia, Focal

Kidney

Hyperplasia, Nos

Liver

Bile Duct

Inflammation, Chronic

Lung

Inflammation, Suppurative

Lymph node

Mandibular Lymph Node

Nephropathy

Mammary gland

Hyperplasia, Nos

Pancreas

Acinus

Alveolar Macrophages

Plasmacytosis

Hyperplasia, Cystic

Atrophy, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_040

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Kidney	Pelvis	Mineralization
		Nephropathy
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Hepatocytes	Cytoplasmic Vacuolization
		Inflammation, Granulomatous
Pituitary gland		Cyst, Nos
Thyroid		Hyperplasia, C Cell

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_041

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Eye

Retina

Atrophy, Nos

Cataract

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Mammary gland

Fibroadenoma

Hyperplasia, Cystic

---

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_042

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Liver	Hepatocytes Hepatocytes Bile Duct	Atrophy, Focal Cytoplasmic Change, Basophilic Hyperplasia, Nos Inflammation, Granulomatous Inflammation, Suppurative
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma Hyperplasia, Cystic
Pituitary gland		Angiectasis Cyst, Nos
Thyroid		C-Cell Carcinoma
Uterus		Hydrometra

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_043

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Clitoral gland

Hyperplasia, Nos

Inflammation, Chronic

Inflammation, Suppurative

Liver

Hepatocytes

Cytoplasmic Change, Basophilic

Inflammation, Granulomatous

Lymph node

Mesenteric Lymph Node

Atrophy, Nos

Mammary gland

Fibroadenoma

Hyperplasia, Cystic

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

**ANIMAL ID:** 3\_044

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

**OBSERVATIONS**

Eye	Retina	Atrophy, Nos Cataract
Kidney	Sclera	Mineralization Inflammation, Chronic Nephropathy Nephrosis, Hydro
Liver	Hepatocytes Hepatocytes Bile Duct	Cytoplasmic Change, Basophilic Cytoplasmic Vacuolization Hyperplasia, Nos
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Atrophy, Nos
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Adenoma, Nos Cyst, Nos
Spinal cord		Degeneration, Nos

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_045

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Liver	Hepatocytes	Cytoplasmic Change, Basophilic
	Hepatocytes	Cytoplasmic Vacuolization
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Lymph node	Mesenteric Lymph Node	Pigmentation, Nos
Pancreas	Acinus	Atrophy, Nos
Pituitary gland		Hyperplasia, Nos
Thyroid		C-Cell Adenoma
Uterus		Hydrometra

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_046

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Moribund Sacrifice

**HISTO:**

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**OBSERVATIONS**

Mammary gland

Fibrosis

Uterus

Hydrometra

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**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

---

**ANIMAL ID:** 3\_047

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

---

**OBSERVATIONS**

Heart		Fibrosis
Liver	Hepatocytes	Atrophy, Focal
	Hepatocytes	Cytoplasmic Change, Basophilic
		Inflammation, Granulomatous
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Ovary		Cyst, Nos
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_048

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Terminal Sacrifice

**HISTO:**

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**OBSERVATIONS**

Heart		Fibrosis
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney		Nephropathy
Lung		Alveolar Macrophages
Mammary gland		Fibroadenoma
		Hyperplasia, Cystic
Pituitary gland		Adenoma, Nos
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** C54911

**Test Type:** Long-Term

**Route:** Gavage

**Species/Strain:** Rat/F344

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

**Test Compound:** C.I. Acid orange 3

**CAS Number:** 6373-74-6

**Date Report Requested:** 10/26/2014

**Time Report Requested:** 17:29:07

**First Dose M/F:** NA / NA

**Lab:** NA

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**ANIMAL ID:** 3\_049

**TRT#:** 3

**SEX:** Female

**DAY ON TEST:**

**DOSE:** 0

**DISP:** Natural Death

**HISTO:**

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**OBSERVATIONS**

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Liver		Inflammation, Chronic
Lung		Alveolar Macrophages
Mammary gland		Hyperplasia, Cystic
Pancreas	Islets	Hyperplasia, Nos
Spleen		Fibrosis
Stomach	Forestomach	Ulcer, Nos
Unspecified	Abdominal Cavity	Lipoma

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

Experiment Number: C54911

Test Type: Long-Term

Route: Gavage

Species/Strain: Rat/F344

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Test Compound: C.I. Acid orange 3

CAS Number: 6373-74-6

Date Report Requested: 10/26/2014

Time Report Requested: 17:29:07

First Dose M/F: NA / NA

Lab: NA

ANIMAL ID: 3\_050

TRT#: 3

SEX: Female

DAY ON TEST:

DOSE: 0

DISP: Terminal Sacrifice

HISTO:

OBSERVATIONS

Adrenal gland	Cortex Nos	Cytoplasmic Vacuolization
Intestine Small	Mesentery Nos	Necrosis, Fat
Kidney	Papilla	Inflammation, Chronic
		Mineralization
		Nephropathy
Liver	Hepatocytes	Atrophy, Focal
	Bile Duct	Hyperplasia, Nos
Lung		Alveolar Macrophages
		Hyperplasia, Alveolar Epithelium
		Inflammation, Granulomatous
Lymph node	Mediastinal Lymph Node	Fibrosis
	Mesenteric Lymph Node	Fibrosis
	Mediastinal Lymph Node	Lymphangiectasis
	Mesenteric Lymph Node	Pigmentation, Nos
	Mandibular Lymph Node	Plasmacytosis
Mammary gland		Hyperplasia, Cystic
Pancreas	Acinus	Atrophy, Nos
	Acinus	Inflammation, Chronic
Pituitary gland		Adenoma, Nos
Thyroid		Hyperplasia, C Cell
Unspecified	Multiple Organs Nos	Leukemia, Mononuclear Cell

PRIMARY CAUSE OF DEATH

-

\*\* END OF REPORT \*\*

\* PROTOCOL REQUIRED TISSUE