

Experiment Number: 88148-05
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/HSD

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**
Test Compound: 3,3',4,4'-Tetrachloroazobenzene
CAS Number: 14047-09-7

Date Report Requested: 10/20/2014
Time Report Requested: 07:48:40
First Dose M/F: NA / NA
Lab: BAT

| | |
|-----------------------------|------------|
| C Number: | C88148B |
| Lock Date: | 10/02/2001 |
| Cage Range: | All |
| Date Range: | All |
| Reasons For Removal: | All |
| Removal Date Range: | All |
| Treatment Groups: | All |
| Study Gender: | Both |
| PWG Approval Date | NONE |

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|-----------------------------------|---------|-----------|-----------|-----------|-----------|------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (0) |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Bile Duct, Hyperplasia | 5 [1.0] | 6 [1.0] | 6 [1.0] | 9 [1.0] | 9 [1.0] | 8 [1.0] |
| Clear Cell Focus | | 1 | 3 | 1 | 1 [1.0] | |
| Fatty Change | | | | | 6 [1.2] | 8 [1.0] |
| Hematopoietic Cell Proliferation | 2 [1.0] | 2 [1.0] | 2 [1.0] | 2 [1.0] | 9 [1.0] | 10 [1.0] |
| Hepatocyte, Hypertrophy | | | 2 [1.0] | 5 [1.2] | 7 [1.3] | 10 [1.5] |
| Infiltration Cellular, Mixed Cell | 8 [1.0] | 8 [1.0] | 9 [1.0] | 10 [1.0] | 10 [1.0] | 10 [1.0] |
| Necrosis | 1 [1.0] | 2 [1.0] | 2 [1.0] | 1 [1.0] | 1 [1.0] | 2 [1.0] |
| Vacuolization Cytoplasmic, Focal | | | 1 [1.0] | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (0) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (0) |
| Hyperplasia, Squamous | | | | | | |
| Tongue | (10) | (0) | (0) | (0) | (0) | (0) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (0) |
| Hypertrophy | 2 [1.5] | | | | | |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (0) |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Test Compound: 3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|---|---------|-----------|-----------|-----------|-----------|------------|
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (0) |
| Cyst | 3 [1.0] | | | | | |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (0) |
| Ultimobranchial Cyst | 5 [1.0] | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Spleen | (10) | (10) | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation Infiltration Cellular, Polymorphnuclr | 2 [1.0] | | 2 [1.5] | 3 [1.0] | 4 [1.0] | 9 [1.3] |
| 1 [1.0] | | | | 1 [1.0] | | |
| Thymus | (9) | (10) | (10) | (10) | (10) | (10) |
| Atrophy | 1 [1.0] | 1 [1.0] | 3 [1.0] | 1 [1.0] | 4 [1.0] | 7 [1.0] |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (10) | (0) | (0) | (0) | (0) | (0) |
| Skin | (10) | (0) | (0) | (0) | (0) | (0) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (9) | (10) | (10) | (10) |
| Alveolar Epith, Metaplasia, Bronchiolar | 2 [1.0] | | 3 [1.0] | 3 [1.0] | 3 [1.0] | 8 [1.0] |
| Alveolus, Hyperplasia, Focal | | | | | | 1 [3.0] |
| Alveolus, Infiltration Cellular, Histiocyte | 1 [1.0] | | | | | |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 88148-05

Test Type: 90-DAY

Route: GAVAGE

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**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: 3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

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Time Report Requested: 07:48:40

First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|---|---------|-----------|-----------|-----------|-----------|------------|
| Infiltration Cellular, Histiocyte Inflammation, Granulomatous, Focal | | | 3 [1.0] | 2 [1.0] | 1 [1.0] | 3 [1.3] |
| Interstitial, Infiltration Cellular, Mononuclear Cl | 1 [1.0] | 3 [1.0] | 3 [1.0] | 5 [1.0] | 5 [1.0] | 9 [1.0] |
| Mineralization | | | | | | |
| Nose | (10) | (0) | (0) | (0) | (0) | (0) |
| Nerve, Degeneration | 3 [1.3] | | | | | |
| Respirat Epith, Hyperplasia | 1 [1.0] | | | | | |
| Respirat Epith, Inflammation | 1 [1.0] | | | | | |
| Squam Epithel, Inflammation | 4 [1.3] | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| None | | | | | | |

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Test Compound: 3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

Date Report Requested: 10/20/2014

Time Report Requested: 07:48:40

First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 30.0 MG/KG | 100.00 MG/KG |
|-----------------------------------|------------|--------------|
| Disposition Summary | | |
| Animals Initially In Study | 10 | 10 |
| Early Deaths | | |
| Survivors | | |
| Terminal Sacrifice | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 |
| ALIMENTARY SYSTEM | | |
| Intestine Small, Duodenum | (0) | (10) |
| Liver | (10) | (10) |
| Bile Duct, Hyperplasia | 7 [1.0] | 5 [1.0] |
| Clear Cell Focus | | |
| Fatty Change | 10 [1.0] | 9 [1.3] |
| Hematopoietic Cell Proliferation | 10 [1.0] | 10 [1.0] |
| Hepatocyte, Hypertrophy | 10 [2.3] | 9 [2.4] |
| Infiltration Cellular, Mixed Cell | 10 [1.0] | 9 [1.2] |
| Necrosis | | |
| Vacuolization Cytoplasmic, Focal | | |
| Pancreas | (0) | (10) |
| Stomach, Forestomach | (0) | (10) |
| Hyperplasia, Squamous | | 1 [1.0] |
| Tongue | (0) | (10) |
| CARDIOVASCULAR SYSTEM | | |
| None | | |
| ENDOCRINE SYSTEM | | |
| Adrenal Cortex | (0) | (10) |
| Hypertrophy | | 1 [1.0] |
| Adrenal Medulla | (0) | (10) |

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 30.0 MG/KG | 100.00 MG/KG |
|---|------------|--------------|
| Pituitary Gland | (0) | (10) |
| Cyst | | |
| Thyroid Gland | (0) | (10) |
| Ultimobranchial Cyst | | 3 [1.0] |
| GENERAL BODY SYSTEM | | |
| None | | |
| GENITAL SYSTEM | | |
| None | | |
| HEMATOPOIETIC SYSTEM | | |
| Spleen | (10) | (9) |
| Hematopoietic Cell Proliferation | 10 [1.5] | 8 [1.0] |
| Infiltration Cellular, Polymorphnuclr | | |
| Thymus | (10) | (8) |
| Atrophy | 10 [1.2] | 6 [1.0] |
| INTEGUMENTARY SYSTEM | | |
| Mammary Gland | (0) | (10) |
| Skin | (0) | (10) |
| MUSCULOSKELETAL SYSTEM | | |
| None | | |
| NERVOUS SYSTEM | | |
| None | | |
| RESPIRATORY SYSTEM | | |
| Lung | (10) | (10) |
| Alveolar Epith, Metaplasia, Bronchiolar | 8 [1.0] | 10 [1.0] |
| Alveolus, Hyperplasia, Focal | | |
| Alveolus, Infiltration Cellular, Histiocyte | | |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat MALE | 30.0 MG/KG | 100.00 MG/KG |
|---|-------------------|---------------------|
| Infiltration Cellular, Histiocyte Inflammation, Granulomatous, Focal Interstitial, Infiltration Cellular, Mononuclear Cl | 10 [1.0] | 10 [1.0] |
| Mineralization | 2 [1.0] | |
| Nose | (0) | (10) |
| Nerve, Degeneration | | 1 [1.0] |
| Respirat Epith, Hyperplasia | | |
| Respirat Epith, Inflammation | | 1 [1.0] |
| Squam Epithel, Inflammation | | 3 [1.0] |

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

END OF MALE DATA

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat FEMALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|-----------------------------------|----------|-----------|-----------|-----------|-----------|------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (0) |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Bile Duct, Hyperplasia | 4 [1.0] | 10 [1.0] | 9 [1.0] | 10 [1.0] | 8 [1.0] | 10 [1.0] |
| Clear Cell Focus | | 1 | | | | 2 |
| Hematopoietic Cell Proliferation | 2 [1.0] | 3 [1.0] | 2 [1.0] | 3 [1.0] | 3 [1.3] | 9 [1.0] |
| Hepatocyte, Hypertrophy | | | | | 1 [1.0] | 6 [1.5] |
| Infiltration Cellular, Mixed Cell | 10 [1.0] | 9 [1.0] | 10 [1.0] | 10 [1.0] | 8 [1.0] | 10 [1.0] |
| Mixed Cell Focus | | | | | | |
| Necrosis | | 1 [1.0] | | 1 [1.0] | | |
| Oral Mucosa | (0) | (0) | (0) | (0) | (0) | (0) |
| Gingival, Inflammation | | | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (0) |
| Acinus, Atrophy | | | | | | |
| Acinus, Inflammation | | | | | | |
| Basophilic Focus | | | | | | |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (0) |
| Diverticulum | 1 | | | | | |
| Epithelium, Hyperplasia, Focal | 1 [1.0] | | | | | |
| Tongue | (10) | (0) | (0) | (0) | (0) | (0) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 88148-05

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

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Test Type: 90-DAY

Test Compound: 3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 07:48:40

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: NA / NA

Species/Strain: Rat/HSD

Lab: BAT

| HSD Rat FEMALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|----------------------------------|---------|-----------|-----------|-----------|-----------|------------|
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (2) | (0) | (0) | (0) |
| Hyperplasia | | | | | | |
| Hypertrophy | 2 [1.5] | | | | | |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (0) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (0) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (0) |
| Ultimobranchial Cyst | 2 [1.0] | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Ovary | (10) | (0) | (0) | (0) | (0) | (0) |
| Uterus | (10) | (0) | (1) | (0) | (0) | (0) |
| Atrophy | | | 1 [4.0] | | | |
| Endometrium, Hyperplasia, Cystic | 1 [1.0] | | | | | |
| Vagina | (10) | (0) | (0) | (0) | (0) | (0) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Spleen | (10) | (2) | (2) | (2) | (2) | (10) |
| Fibrosis | | | | | | |
| Hematopoietic Cell Proliferation | 3 [1.7] | 2 [2.0] | 2 [1.5] | 2 [1.5] | 1 [3.0] | 5 [1.0] |
| Pigmentation, Hemosiderin | | | 1 [1.0] | | 1 [1.0] | 4 [1.0] |
| Thymus | (10) | (10) | (10) | (10) | (10) | (10) |
| Atrophy | | 2 [1.0] | 8 [1.0] | 7 [1.0] | 6 [1.0] | 8 [1.0] |
| Cyst | | | | | 1 [1.0] | 1 [1.0] |
| Hyperplasia, Squamous | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (9) | (0) | (0) | (0) | (0) | (0) |

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat FEMALE | 0 MG/KG | 0.1 MG/KG | 0.3 MG/KG | 1.0 MG/KG | 3.0 MG/KG | 10.0 MG/KG |
|---|---------|-----------|-----------|-----------|-----------|------------|
| Skin | (10) | (0) | (0) | (0) | (0) | (0) |
| Subcut Tiss, Inflammation, Suppurative | 1 [2.0] | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (10) | (10) | (10) | (9) |
| Alveolar Epith, Metaplasia, Bronchiolar Fibrosis, Focal | 1 [1.0] | 2 [1.0] | | 1 [1.0] | | |
| Infiltration Cellular, Histiocyte | | 2 [1.0] | 3 [1.0] | 1 [1.0] | 1 [1.0] | |
| Infiltration Cellular, Mononuclear Cl Interstitial, Infiltration Cellular, Mononuclear Cl | | 1 [1.0] | 2 [1.0] | 2 [1.0] | 2 [1.0] | |
| Perivascular, Infiltration Cellular, Polymorphnuclr | 1 [1.0] | | | | | |
| Nose | (10) | (0) | (0) | (0) | (0) | (0) |
| Nerve, Degeneration | 3 [1.0] | | | | | |
| Squam Epithel, Inflammation | 1 [1.0] | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (0) | (1) | (0) | (0) | (2) | (1) |
| Hemorrhage | | | | | 1 [2.0] | |
| Inflammation, Chronic Active | | 1 [4.0] | | | 1 [4.0] | 1 [4.0] |
| URINARY SYSTEM | | | | | | |
| None | | | | | | |

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Test Compound: 3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

Date Report Requested: 10/20/2014

Time Report Requested: 07:48:41

First Dose M/F: NA / NA

Lab: BAT

| HSD Rat FEMALE | 30.0 MG/KG | 100.0 MG/KG |
|----------------------------------|------------|-------------|
| Disposition Summary | | |
| Animals Initially In Study | 10 | 10 |
| Early Deaths | | |
| Survivors | | |
| Terminal Sacrifice | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 |

ALIMENTARY SYSTEM

| | | |
|-----------------------------------|----------|----------|
| Intestine Small, Duodenum | (0) | (10) |
| Liver | (10) | (10) |
| Bile Duct, Hyperplasia | 7 [1.0] | 5 [1.0] |
| Clear Cell Focus | | 2 |
| Hematopoietic Cell Proliferation | 10 [1.0] | 10 [1.0] |
| Hepatocyte, Hypertrophy | 6 [1.3] | 5 [1.2] |
| Infiltration Cellular, Mixed Cell | 10 [1.0] | 9 [1.0] |
| Mixed Cell Focus | 1 | |
| Necrosis | | |
| Oral Mucosa | (0) | (2) |
| Gingival, Inflammation | | 2 [1.0] |
| Pancreas | (0) | (10) |
| Acinus, Atrophy | | 2 [1.0] |
| Acinus, Inflammation | | 1 [1.0] |
| Basophilic Focus | | 1 [1.0] |
| Stomach, Forestomach | (0) | (10) |
| Diverticulum | | |
| Epithelium, Hyperplasia, Focal | | |
| Tongue | (0) | (10) |

CARDIOVASCULAR SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA

Lab: BAT

| HSD Rat FEMALE | 30.0 MG/KG | 100.0 MG/KG |
|----------------------------------|------------|-------------|
| ENDOCRINE SYSTEM | | |
| Adrenal Cortex | (1) | (10) |
| Hyperplasia | | 1 [1.0] |
| Hypertrophy | | |
| Adrenal Medulla | (0) | (10) |
| Pituitary Gland | (0) | (10) |
| Thyroid Gland | (0) | (10) |
| Ultimobranchial Cyst | | 2 [2.0] |
| GENERAL BODY SYSTEM | | |
| None | | |
| GENITAL SYSTEM | | |
| Ovary | (0) | (10) |
| Uterus | (0) | (10) |
| Atrophy | | |
| Endometrium, Hyperplasia, Cystic | | |
| Vagina | (0) | (10) |
| HEMATOPOIETIC SYSTEM | | |
| Spleen | (10) | (10) |
| Fibrosis | | 1 [1.0] |
| Hematopoietic Cell Proliferation | 2 [1.5] | |
| Pigmentation, Hemosiderin | 7 [1.0] | 7 [1.0] |
| Thymus | (10) | (10) |
| Atrophy | 9 [1.1] | 7 [1.3] |
| Cyst | 1 [1.0] | |
| Hyperplasia, Squamous | 1 [1.0] | |
| INTEGUMENTARY SYSTEM | | |
| Mammary Gland | (0) | (10) |

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Experiment Number: 88148-05

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/HSD

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: 3,3',4,4'-Tetrachloroazobenzene

CAS Number: 14047-09-7

Date Report Requested: 10/20/2014

Time Report Requested: 07:48:41

First Dose M/F: NA / NA

Lab: BAT

| HSD Rat FEMALE | 30.0 MG/KG | 100.0 MG/KG |
|--|------------|-------------|
| Skin | (0) | (10) |
| Subcut Tiss, Inflammation, Suppurative | | |
| MUSCULOSKELETAL SYSTEM | | |
| None | | |
| NERVOUS SYSTEM | | |
| None | | |
| RESPIRATORY SYSTEM | | |
| Lung | (9) | (10) |
| Alveolar Epith, Metaplasia, Bronchiolar Fibrosis, Focal | 3 [1.0] | 3 [1.0] |
| Infiltration Cellular, Histiocyte | | 4 [1.3] |
| Infiltration Cellular, Mononuclear Cl | | 1 [1.0] |
| Interstitial, Infiltration Cellular, Mononuclear Cl | 2 [1.0] | 6 [1.2] |
| Perivascular, Infiltration Cellular, Polymorphnuclr | | |
| Nose | (0) | (10) |
| Nerve, Degeneration | | 2 [1.5] |
| Squam Epithel, Inflammation | | 4 [1.0] |
| SPECIAL SENSES SYSTEM | | |
| Eye | (0) | (0) |
| Hemorrhage | | |
| Inflammation, Chronic Active | | |
| URINARY SYSTEM | | |
| None | | |

**** END OF REPORT ****

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)