

Experiment Number: 20601 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Antimony trioxide
CAS Number: 1309-64-4

Date Report Requested: 10/15/2014
Time Report Requested: 14:18:25
First Dose M/F: 09/22/08 / 09/22/08
Lab: BNW

F1_53 Wk. SSAC_RE

NTP Study Number: C20601
Lock Date: 06/13/2011
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25017 SSAC
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.2_002
PWG Approval Date: NONE

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| Wistar Han RATS MALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|---|---------|---------|----------|----------|
| Disposition Summary | | | | |
| Animals Initially In Study | 60 | 60 | 60 | 60 |
| Scheduled Sacrifice | 10 | 10 | 10 | 10 |
| Early Deaths | | | | |
| Survivors | | | | |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | |
| Esophagus | (10) | (10) | (10) | (10) |
| Intestine Large, Cecum | (10) | (10) | (10) | (10) |
| Intestine Large, Colon | (10) | (10) | (10) | (10) |
| Intestine Large, Rectum | (10) | (9) | (10) | (10) |
| Intestine Small, Duodenum | (10) | (10) | (10) | (10) |
| Intestine Small, Ileum | (10) | (10) | (10) | (10) |
| Intestine Small, Jejunum | (10) | (10) | (10) | (10) |
| Liver | (10) | (10) | (10) | (10) |
| Congestion | | 1 (10%) | | |
| Pancreas | (10) | (10) | (10) | (10) |
| Atrophy | 3 (30%) | 2 (20%) | 2 (20%) | |
| Inflammation, Chronic Active | 3 (30%) | 1 (10%) | 1 (10%) | |
| Arteriole, Inflammation, Chronic Active | | | 1 (10%) | |
| Salivary Glands | (10) | (10) | (10) | (10) |
| Stomach, Forestomach | (10) | (10) | (10) | (10) |
| Ulcer | 1 (10%) | | | |
| Stomach, Glandular | (10) | (10) | (10) | (10) |
| Inflammation, Chronic Active | 1 (10%) | | | 2 (20%) |
| CARDIOVASCULAR SYSTEM | | | | |
| Blood Vessel | (10) | (10) | (10) | (10) |
| Heart | (10) | (10) | (10) | (10) |
| Cardiomyopathy | 3 (30%) | 2 (20%) | 5 (50%) | 2 (20%) |

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

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| Wistar Han RATS MALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|-----------------------------------|---------|----------|-----------|-----------|
| ENDOCRINE SYSTEM | | | | |
| Adrenal Cortex | (10) | (10) | (10) | (10) |
| Hyperplasia | 1 (10%) | 3 (30%) | 2 (20%) | 3 (30%) |
| Adrenal Medulla | (10) | (10) | (9) | (10) |
| Hypertrophy | 1 (10%) | | | |
| Islets, Pancreatic | (10) | (10) | (10) | (10) |
| Parathyroid Gland | (10) | (10) | (9) | (8) |
| Pituitary Gland | (10) | (10) | (10) | (10) |
| Pars Distalis, Hyperplasia | 1 (10%) | | | |
| Thyroid Gland | (10) | (10) | (10) | (10) |
| Hyperplasia, Squamous | | 1 (10%) | | |
| GENERAL BODY SYSTEM | | | | |
| None | | | | |
| GENITAL SYSTEM | | | | |
| Epididymis | (10) | (10) | (10) | (10) |
| Preputial Gland | (10) | (10) | (10) | (9) |
| Inflammation, Chronic Active | 4 (40%) | 2 (20%) | 6 (60%) | 3 (33%) |
| Prostate | (10) | (10) | (10) | (10) |
| Inflammation, Suppurative | 3 (30%) | | | 1 (10%) |
| Epithelium, Hyperplasia | | 1 (10%) | | |
| Seminal Vesicle | (10) | (10) | (10) | (10) |
| Testes | (10) | (10) | (10) | (10) |
| Germinal Epithelium, Degeneration | 2 (20%) | 2 (20%) | | |
| HEMATOPOIETIC SYSTEM | | | | |
| Bone Marrow | (10) | (10) | (10) | (10) |
| Lymph Node, Bronchial | (9) | (8) | (10) | (10) |
| Foreign Body | | 8 (100%) | 10 (100%) | 10 (100%) |

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

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| Wistar Han RATS MALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|-----------------------------------|---------|-----------|-----------|-----------|
| Hyperplasia, Lymphoid | | 2 (25%) | 5 (50%) | 2 (20%) |
| Lymph Node, Mandibular | (10) | (9) | (9) | (8) |
| Lymph Node, Mediastinal | (10) | (8) | (10) | (9) |
| Foreign Body | | 8 (100%) | 6 (60%) | 6 (67%) |
| Hyperplasia, Lymphoid | | 2 (25%) | 6 (60%) | 3 (33%) |
| Pigmentation | 5 (50%) | 5 (63%) | 8 (80%) | 5 (56%) |
| Lymph Node, Mesenteric | (10) | (10) | (10) | (10) |
| Spleen | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation | 2 (20%) | 5 (50%) | 2 (20%) | 4 (40%) |
| Thymus | (10) | (10) | (10) | (10) |
| INTEGUMENTARY SYSTEM | | | | |
| Mammary Gland | (4) | (1) | (1) | (3) |
| Skin | (10) | (10) | (10) | (10) |
| Fibrosis | | | 1 (10%) | |
| MUSCULOSKELETAL SYSTEM | | | | |
| Bone | (10) | (10) | (10) | (10) |
| NERVOUS SYSTEM | | | | |
| Brain | (10) | (10) | (10) | (10) |
| RESPIRATORY SYSTEM | | | | |
| Larynx | (10) | (10) | (10) | (10) |
| Foreign Body | | 10 (100%) | 10 (100%) | 10 (100%) |
| Infiltration Cellular, Lymphocyte | 1 (10%) | | | |
| Lung | (10) | (10) | (10) | (10) |
| Fibrosis | | 10 (100%) | 10 (100%) | 10 (100%) |
| Foreign Body | | 10 (100%) | 10 (100%) | 10 (100%) |

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

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| Wistar Han RATS MALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|---|---------|-----------|-----------|-----------|
| Inflammation, Chronic Active | 1 (10%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Metaplasia, Osseous | | | 1 (10%) | |
| Proteinosis | | 9 (90%) | 10 (100%) | 10 (100%) |
| Alveolar Epithelium, Hyperplasia | | 10 (100%) | 10 (100%) | 10 (100%) |
| Alveolus, Inflammation, Suppurative | | 1 (10%) | 2 (20%) | 2 (20%) |
| Bronchiole, Epithelium, Hyperplasia | | 5 (50%) | 5 (50%) | 6 (60%) |
| Perivascular, Infiltration Cellular, Lymphocyte | | 4 (40%) | 4 (40%) | 3 (30%) |
| Nose | (10) | (10) | (10) | (10) |
| Foreign Body | | | 1 (10%) | 9 (90%) |
| Inflammation, Suppurative | | 1 (10%) | | 1 (10%) |
| Glands, Respiratory Epithelium, Cyst | | | 1 (10%) | |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | 3 (30%) | 1 (10%) | 4 (40%) | 2 (20%) |
| Respiratory Epithelium, Accumulation, Hyaline Droplet | 2 (20%) | | | |
| Respiratory Epithelium, Hyperplasia | | | 1 (10%) | 2 (20%) |
| Trachea | (10) | (10) | (10) | (10) |
| Foreign Body | | 8 (80%) | 9 (90%) | 10 (100%) |
| Infiltration Cellular, Polymorphonuclear | | | | 1 (10%) |

SPECIAL SENSES SYSTEM

| | | | | |
|--------------------|---------|---------|---------|------|
| Eye | (10) | (10) | (10) | (10) |
| Lens, Degeneration | | | 1 (10%) | |
| Retina, Atrophy | 2 (20%) | 1 (10%) | | |
| Harderian Gland | (10) | (10) | (10) | (10) |

URINARY SYSTEM

| | | | | |
|--------------------------------------|---------|---------|---------|---------|
| Kidney | (10) | (10) | (10) | (10) |
| Nephropathy | 6 (60%) | 3 (30%) | 4 (40%) | 5 (50%) |
| Pelvis, Dilatation | 1 (10%) | | | |
| Pelvis, Inflammation, Chronic Active | | 1 (10%) | | |
| Urinary Bladder | (10) | (10) | (10) | (10) |
| Calculus Gross Observation | | | 3 (30%) | 2 (20%) |

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

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Wistar Han RATS MALE

Control

3 mg/m3

10 mg/m3

30 mg/m3

*** END OF MALE ***

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| Wistar Han RATS FEMALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|------------------------|---------|---------|----------|----------|
|------------------------|---------|---------|----------|----------|

Disposition Summary

| | | | | |
|----------------------------------|----|----|----|----|
| Animals Initially In Study | 60 | 60 | 60 | 60 |
| Scheduled Sacrifice | 10 | 10 | 10 | 10 |
| Early Deaths | | | | |
| Survivors | | | | |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 |

ALIMENTARY SYSTEM

| | | | | |
|-----------------------------------|---------|---------|---------|---------|
| Esophagus | (10) | (10) | (9) | (10) |
| Intestine Large, Cecum | (10) | (10) | (10) | (10) |
| Intestine Large, Colon | (10) | (10) | (10) | (10) |
| Intestine Large, Rectum | (10) | (10) | (10) | (10) |
| Intestine Small, Duodenum | (10) | (10) | (10) | (10) |
| Intestine Small, Ileum | (10) | (10) | (10) | (10) |
| Intestine Small, Jejunum | (10) | (10) | (10) | (10) |
| Liver | (10) | (10) | (10) | (10) |
| Basophilic Focus | 1 (10%) | | | |
| Hematopoietic Cell Proliferation | 1 (10%) | | | |
| Hepatodiaphragmatic Nodule | 1 (10%) | | | |
| Infiltration Cellular, Histiocyte | | | 1 (10%) | |
| Pigmentation, Hemosiderin | | | 1 (10%) | |
| Pancreas | (10) | (10) | (10) | (10) |
| Atrophy | | | 1 (10%) | 2 (20%) |
| Basophilic Focus | | 1 (10%) | | |
| Inflammation, Chronic Active | | | 1 (10%) | 1 (10%) |
| Artery, Fibrosis | | 1 (10%) | | |
| Salivary Glands | (10) | (10) | (10) | (10) |
| Stomach, Forestomach | (10) | (10) | (10) | (10) |
| Stomach, Glandular | (10) | (10) | (10) | (10) |

CARDIOVASCULAR SYSTEM

| | | | | |
|--------------|------|------|------|------|
| Blood Vessel | (10) | (10) | (10) | (10) |
|--------------|------|------|------|------|

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| Wistar Han RATS FEMALE | Control | 3 mg/m3 | 10 mg/m3 | 30 mg/m3 |
|------------------------|---------|---------|----------|----------|
| Heart | (10) | (10) | (10) | (10) |
| Cardiomyopathy | | 3 (30%) | | 1 (10%) |
| Mineralization | 1 (10%) | | | |

ENDOCRINE SYSTEM

| | | | | |
|----------------------------|---------|---------|---------|---------|
| Adrenal Cortex | (10) | (10) | (10) | (10) |
| Hyperplasia | | 1 (10%) | 1 (10%) | 1 (10%) |
| Adrenal Medulla | (10) | (10) | (10) | (10) |
| Islets, Pancreatic | (10) | (10) | (10) | (10) |
| Parathyroid Gland | (10) | (8) | (8) | (10) |
| Pituitary Gland | (10) | (10) | (10) | (10) |
| Pars Distalis, Hyperplasia | 2 (20%) | 2 (20%) | | 1 (10%) |
| Thyroid Gland | (10) | (10) | (10) | (10) |
| C-cell, Hyperplasia | | | | 1 (10%) |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | |
|--|---------|---------|---------|---------|
| Clitoral Gland | (10) | (10) | (10) | (10) |
| Inflammation, Chronic Active | 4 (40%) | 3 (30%) | 3 (30%) | 1 (10%) |
| Ovary | (10) | (10) | (10) | (10) |
| Cyst | 2 (20%) | 1 (10%) | 4 (40%) | |
| Uterus | (10) | (10) | (10) | (10) |
| Dilatation | | 1 (10%) | | |
| Endometrial Glands, Metaplasia, Squamous | | | 1 (10%) | 1 (10%) |

HEMATOPOIETIC SYSTEM

| | | | | |
|-------------|------|------|------|------|
| Bone Marrow | (10) | (10) | (10) | (10) |
|-------------|------|------|------|------|

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|----------------------------------|---------|----------|----------|----------|
| Hyperplasia | 1 (10%) | 1 (10%) | 3 (30%) | |
| Lymph Node, Bronchial | (7) | (8) | (9) | (5) |
| Foreign Body | | 7 (88%) | 9 (100%) | 4 (80%) |
| Hyperplasia, Lymphoid | | 4 (50%) | 2 (22%) | 1 (20%) |
| Pigmentation | | | | 1 (20%) |
| Lymph Node, Mandibular | (10) | (10) | (10) | (8) |
| Lymph Node, Mediastinal | (10) | (9) | (10) | (10) |
| Foreign Body | | 9 (100%) | 5 (50%) | 6 (60%) |
| Hyperplasia, Lymphoid | | 8 (89%) | | 3 (30%) |
| Pigmentation | 8 (80%) | 8 (89%) | 8 (80%) | 8 (80%) |
| Lymph Node, Mesenteric | (10) | (10) | (10) | (10) |
| Spleen | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation | 4 (40%) | 6 (60%) | 6 (60%) | 7 (70%) |
| Thymus | (10) | (10) | (10) | (10) |
| Cyst | 1 (10%) | | 2 (20%) | |
| Hyperplasia, Squamous | | 1 (10%) | | 1 (10%) |
| INTEGUMENTARY SYSTEM | | | | |
| Mammary Gland | (10) | (10) | (10) | (10) |
| Skin | (10) | (10) | (10) | (10) |
| Cyst, Squamous | 1 (10%) | | | |
| MUSCULOSKELETAL SYSTEM | | | | |
| Bone | (10) | (10) | (10) | (10) |
| NERVOUS SYSTEM | | | | |
| Brain | (10) | (10) | (10) | (10) |
| RESPIRATORY SYSTEM | | | | |

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|---|---------|-----------|-----------|-----------|
| Larynx | (10) | (10) | (10) | (10) |
| Foreign Body | | 10 (100%) | 10 (100%) | 10 (100%) |
| Lung | (10) | (10) | (10) | (10) |
| Fibrosis | | 10 (100%) | 10 (100%) | 10 (100%) |
| Foreign Body | | 10 (100%) | 10 (100%) | 10 (100%) |
| Hemorrhage | | | 1 (10%) | 1 (10%) |
| Inflammation, Chronic Active | 2 (20%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Proteinosis | | 10 (100%) | 10 (100%) | 10 (100%) |
| Alveolar Epithelium, Hyperplasia | | 10 (100%) | 10 (100%) | 10 (100%) |
| Alveolus, Inflammation, Suppurative | | 1 (10%) | | 3 (30%) |
| Bronchiole, Epithelium, Hyperplasia | | 1 (10%) | | 3 (30%) |
| Perivascular, Infiltration Cellular, Lymphocyte | | 4 (40%) | 5 (50%) | 3 (30%) |
| Nose | (10) | (10) | (10) | (10) |
| Foreign Body | | | | 4 (40%) |
| Metaplasia, Mucous | | | | 1 (10%) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | 2 (20%) | 2 (20%) | 1 (10%) | 2 (20%) |
| Respiratory Epithelium, Accumulation, Hyaline Droplet | | 1 (10%) | | 1 (10%) |
| Respiratory Epithelium, Hyperplasia | | 1 (10%) | | 2 (20%) |
| Respiratory Epithelium, Metaplasia, Squamous | | | | 1 (10%) |
| Trachea | (10) | (10) | (10) | (10) |
| Foreign Body | | 6 (60%) | 10 (100%) | 10 (100%) |

SPECIAL SENSES SYSTEM

| | | | | |
|--------------------|---------|---------|---------|---------|
| Eye | (10) | (10) | (10) | (10) |
| Lens, Degeneration | | 1 (10%) | | |
| Retina, Atrophy | 1 (10%) | | 1 (10%) | 1 (10%) |
| Harderian Gland | (10) | (10) | (10) | (10) |

URINARY SYSTEM

| | | | | |
|---------------------------------|------|---------|---------|------|
| Kidney | (10) | (10) | (10) | (10) |
| Calculus Micro Observation Only | | 1 (10%) | 1 (10%) | |

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|-------------------------------|----------------|----------------|-----------------|-----------------|
| Nephropathy | | 2 (20%) | 1 (10%) | 2 (20%) |
| Cortex, Vein, Dilatation | | | | 1 (10%) |
| Urinary Bladder | (10) | (10) | (10) | (10) |

*** END OF REPORT ***

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