

TDMS No. 20519 - 02

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Metal working fluids (Syntilo 1023)

CAS Number: SYNTILO1023

Date Report Requested: 05/18/2011

Time Report Requested: 08:14:39

First Dose M/F: 11/03/08 / 11/03/08

Lab: BNW

F1_M3

C Number: C20519
Lock Date: 06/09/2009
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.4.0.0_003
PWG Approval Date: NONE

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE

Control

25 mg/m3

50 mg/m3

100 mg/m3

200 mg/m3

400 mg/m3

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

| | | | | | | |
|---------------------------|---------|-----|-----|-----|-----|---------|
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Gallbladder | (9) | (0) | (0) | (0) | (0) | (5) |
| Inflammation, Neutrophil | | | | | | 1 (20%) |
| Mineralization | 1 (11%) | | | | | |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (0) | (0) | (0) | (0) | (10) |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |

CARDIOVASCULAR SYSTEM

| | | | | | | |
|--------------|------|-----|-----|-----|-----|------|
| Blood Vessel | (10) | (0) | (0) | (0) | (0) | (10) |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |

ENDOCRINE SYSTEM

| | | | | | | |
|-----------------|------|-----|-----|-----|-----|------|
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |

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

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CAS Number: SYNTILO1023

First Dose M/F: 11/03/08 / 11/03/08

Species/Strain: MICE/B6C3F1

Lab: BNW

| B6C3F1 MICE MALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|--------------------|---------|----------|----------|-----------|-----------|-----------|
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (0) | (10) |
| Parathyroid Gland | (6) | (0) | (0) | (0) | (0) | (6) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (1) | (10) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | | | |
|-----------------|------|-----|-----|-----|-----|------|
| Epididymis | (10) | (0) | (0) | (0) | (0) | (10) |
| Preputial Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Prostate | (10) | (0) | (0) | (0) | (0) | (10) |
| Seminal Vesicle | (10) | (0) | (0) | (0) | (0) | (10) |
| Testes | (10) | (0) | (0) | (0) | (0) | (10) |

HEMATOPOIETIC SYSTEM

| | | | | | | |
|-------------------------|------|-----|-----|-----|-----|------|
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Bronchial | (8) | (0) | (0) | (0) | (0) | (9) |
| Lymph Node, Mandibular | (7) | (0) | (0) | (0) | (0) | (7) |
| Lymph Node, Mediastinal | (6) | (0) | (0) | (0) | (0) | (4) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (1) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |

INTEGUMENTARY SYSTEM

| | | | | | | |
|------|------|-----|-----|-----|-----|------|
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |
|------|------|-----|-----|-----|-----|------|

MUSCULOSKELETAL SYSTEM

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

| B6C3F1 MICE MALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|---|---------|-----------|-----------|-----------|-----------|-----------|
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Larynx | (10) | (10) | (10) | (10) | (10) | (10) |
| Erosion, Focal | | | | | 2 (20%) | |
| Inflammation, Chronic Active | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Metaplasia, Squamous | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Ulcer, Focal | | | | | 3 (30%) | 8 (80%) |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte | | | | | | 1 (10%) |
| Arteriole, Hypertrophy | | | | | | 1 (10%) |
| Bronchiole, Goblet Cell, Hyperplasia | | | | | 1 (10%) | 1 (10%) |
| Perivascular, Inflammation, Chronic Active | | | | | 1 (10%) | 1 (10%) |
| Nose | (10) | (10) | (10) | (10) | (10) | (10) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | | | | | 2 (20%) | 8 (80%) |
| Respiratory Epithelium, Accumulation, Hyaline Droplet | | | | 1 (10%) | 7 (70%) | 9 (90%) |
| Trachea | (10) | (10) | (10) | (9) | (10) | (10) |
| Inflammation, Chronic | 1 (10%) | | | | 1 (10%) | |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |

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

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Date Report Requested: 05/18/2011

Time Report Requested: 08:14:39

First Dose M/F: 11/03/08 / 11/03/08

Lab: BNW

| B6C3F1 MICE MALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|------------------------|---------|----------|----------|-----------|-----------|-----------|
| Casts | | | | | | 1 (10%) |
| Nephropathy | 1 (10%) | | | | | 4 (40%) |
| Cortex, Infarct, Focal | | | | | | 1 (10%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

*** END OF MALE ***

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

| B6C3F1 MICE FEMALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|--------------------|---------|----------|----------|-----------|-----------|-----------|
|--------------------|---------|----------|----------|-----------|-----------|-----------|

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

| | | | | | | |
|--|---------|-----|-----|-----|-----|---------|
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Gallbladder | (10) | (0) | (0) | (0) | (0) | (8) |
| Inflammation, Neutrophil | 1 (10%) | | | | | |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Rectum | (9) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (0) | (0) | (0) | (0) | (10) |
| Necrosis, Focal | 1 (10%) | | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Periductular, Inflammation, Focal, Chronic | | | | | | 1 (10%) |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |

CARDIOVASCULAR SYSTEM

| | | | | | | |
|--------------|------|-----|-----|-----|-----|------|
| Blood Vessel | (10) | (0) | (0) | (0) | (0) | (10) |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |

ENDOCRINE SYSTEM

| | | | | | | |
|----------------|------|-----|-----|-----|-----|------|
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
|----------------|------|-----|-----|-----|-----|------|

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

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Species/Strain: MICE/B6C3F1

Lab: BNW

| B6C3F1 MICE FEMALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|--------------------|---------|----------|----------|-----------|-----------|-----------|
| Adrenal Medulla | (9) | (0) | (0) | (0) | (0) | (10) |
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (0) | (10) |
| Parathyroid Gland | (3) | (0) | (0) | (0) | (0) | (9) |
| Cyst, Multiple | | | | | | 1 (11%) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | | | |
|----------------|------|-----|-----|-----|-----|------|
| Clitoral Gland | (7) | (0) | (0) | (0) | (0) | (10) |
| Ovary | (10) | (0) | (0) | (0) | (0) | (10) |
| Uterus | (10) | (0) | (0) | (0) | (0) | (10) |

HEMATOPOIETIC SYSTEM

| | | | | | | |
|-------------------------|------|-----|-----|-----|-----|------|
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Bronchial | (8) | (0) | (0) | (0) | (0) | (9) |
| Lymph Node, Mandibular | (7) | (0) | (0) | (0) | (0) | (8) |
| Lymph Node, Mediastinal | (3) | (0) | (0) | (0) | (0) | (3) |
| Lymph Node, Mesenteric | (9) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |

INTEGUMENTARY SYSTEM

| | | | | | | |
|---------------|------|-----|-----|-----|-----|------|
| Mammary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |

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

| B6C3F1 MICE FEMALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|---|---------|----------|-----------|-----------|-----------|-----------|
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Larynx | (9) | (9) | (10) | (10) | (10) | (10) |
| Erosion, Focal | | | 2 (20%) | 3 (30%) | 1 (10%) | |
| Inflammation, Chronic Active | | 9 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Metaplasia, Squamous | 1 (11%) | 9 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Ulcer, Focal | | | | 2 (20%) | 6 (60%) | 7 (70%) |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte | | | | | 1 (10%) | 3 (30%) |
| Arteriole, Hypertrophy | | | | 1 (10%) | 2 (20%) | 3 (30%) |
| Bronchiole, Goblet Cell, Hyperplasia | | | | 1 (10%) | 1 (10%) | 3 (30%) |
| Perivascular, Inflammation, Chronic Active | | | | 1 (10%) | 1 (10%) | 3 (30%) |
| Nose | (10) | (10) | (10) | (10) | (10) | (10) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet | 1 (10%) | | | 1 (10%) | 2 (20%) | 9 (90%) |
| Respiratory Epithelium, Accumulation, Hyaline Droplet | | | | 6 (60%) | 9 (90%) | 10 (100%) |
| Trachea | (10) | (10) | (10) | (9) | (10) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| URINARY SYSTEM | | | | | | |

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

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Lab: BNW

| B6C3F1 MICE FEMALE | Control | 25 mg/m3 | 50 mg/m3 | 100 mg/m3 | 200 mg/m3 | 400 mg/m3 |
|--------------------|---------|----------|----------|-----------|-----------|-----------|
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Nephropathy | 1 (10%) | | | | | 1 (10%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

*** END OF REPORT ***

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