

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

F1_RE

C Number: C20523

Lock Date: 02/24/2009

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.3.1

PWG Approval Date: NONE

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS MALE	0 mg/m3	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)
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)
Inflammation, Chronic Active						1 (10%)
Metaplasia, Squamous						1 (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)	(1)	(0)	(0)	(0)	(10)
Inflammation, Focal, Chronic Active		1 (100%)				
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 (10%)					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						1 (10%)
Stomach, Glandular	(10)	(0)	(0)	(1)	(0)	(10)
Atrophy				1 (100%)		

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	1 (10%)					1 (10%)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS MALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
----------------------	---------	----------	----------	-----------	-----------	-----------

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule	4 (40%)					2 (20%)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(9)
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)
Inflammation, Chronic	3 (30%)					2 (20%)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 (10%)					2 (20%)
Inflammation, Chronic Active	1 (10%)					
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(1)	(0)	(10)
Germinal Epithelium, Degeneration				1 (100%)		

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Bronchial	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mediastinal	(10)	(0)	(0)	(0)	(0)	(9)
Hyperplasia, Lymphoid						1 (11%)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS MALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(2)	(0)	(0)	(0)	(0)	(1)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
Ulcer			1 (100%)			
MUSCULOSKELETAL SYSTEM						
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)
Hyperplasia, Squamous		8 (80%)	8 (80%)	7 (70%)	10 (100%)	10 (100%)
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		1 (10%)				
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis			10 (100%)	10 (100%)	10 (100%)	10 (100%)
Infiltration Cellular, Histiocyte			1 (10%)	10 (100%)	10 (100%)	10 (100%)
Inflammation, Chronic Active			8 (80%)	10 (100%)	10 (100%)	10 (100%)
Metaplasia, Osseous		2 (20%)	4 (40%)			
Pigmentation			3 (30%)	3 (30%)	1 (10%)	3 (30%)
Artery, Mineralization	1 (10%)					
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS MALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
Inflammation, Chronic	1 (10%)					
Necrosis	1 (10%)					
Goblet Cell, Hyperplasia			1 (10%)	3 (30%)	10 (100%)	8 (80%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	1 (10%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 (100%)	10 (100%)	10 (100%)	10 (100%)	7 (70%)
Respiratory Epithelium, Hyperplasia					9 (90%)	10 (100%)
Respiratory Epithelium, Metaplasia, Squamous					4 (40%)	7 (70%)
Respiratory Epithelium, Necrosis					1 (10%)	
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	2 (20%)					1 (10%)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
Inflammation, Chronic Active	1 (10%)					1 (10%)
Renal Tubule, Regeneration	2 (20%)					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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS FEMALE	0 mg/m3	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)
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)	(1)	(10)
Fibrosis					1 (100%)	
Serosa, Mineralization					1 (100%)	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, 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)
Accessory Adrenal Cortical Nodule	2 (20%)					3 (30%)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS FEMALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic						3 (30%)
Inflammation, Chronic Active	1 (10%)					
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Oviduct	(0)	(0)	(0)	(0)	(0)	(1)
Infiltration Cellular, Polymorphonuclear						1 (100%)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
Endometrium, Hyperplasia, Cystic						2 (20%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(1)	(1)
Deep Cervical, Infiltration Cellular, Polymorphonuclear						1 (100%)
Renal, Infiltration Cellular, Mixed Cell					1 (100%)	
Lymph Node, Bronchial	(7)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Mediastinal	(9)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS FEMALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
------------------------	---------	----------	----------	-----------	-----------	-----------

INTEGUMENTARY SYSTEM

Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)

MUSCULOSKELETAL SYSTEM

Bone	(10)	(0)	(0)	(0)	(1)	(10)
Maxilla, Inflammation, Chronic Active					1 (100%)	

NERVOUS SYSTEM

Brain	(10)	(0)	(0)	(0)	(0)	(10)
-------	------	-----	-----	-----	-----	------

RESPIRATORY SYSTEM

Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous		8 (80%)	4 (40%)	7 (70%)	8 (80%)	10 (100%)
Inflammation, Chronic	1 (10%)					
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%)
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis			10 (100%)	10 (100%)	10 (100%)	10 (100%)
Infiltration Cellular, Histiocyte			1 (10%)	10 (100%)	10 (100%)	10 (100%)
Inflammation, Chronic Active	3 (30%)		9 (90%)	10 (100%)	10 (100%)	10 (100%)
Metaplasia, Osseous		1 (10%)				
Metaplasia, Squamous			1 (10%)			
Mineralization				1 (10%)		
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Foreign Body			1 (10%)		1 (10%)	
Inflammation, Suppurative		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Goblet Cell, Hyperplasia				3 (30%)	9 (90%)	9 (90%)

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

TDMS No. 20523 - 01

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

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

Metal working fluids (Trim VX)

CAS Number: TRIMVX

Date Report Requested: 03/18/2011

Time Report Requested: 13:35:18

First Dose M/F: 07/14/08 / 07/14/08

Lab: BNW

Wistar Han RATS FEMALE	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3
Olfactory Epithelium, Accumulation, Hyaline Droplet		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 (100%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
Respiratory Epithelium, Hyperplasia				1 (10%)	10 (100%)	10 (100%)
Respiratory Epithelium, Metaplasia, Squamous				2 (20%)	5 (50%)	7 (70%)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 (10%)					2 (20%)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(1)	(1)	(10)
Dilatation					1 (100%)	
Infarct, Multiple				1 (100%)		
Inflammation, Chronic Active	1 (10%)					
Bilateral, Pelvis, Inflammation, Chronic Active					1 (100%)	
Pelvis, Inflammation, Chronic	1 (10%)					
Pelvis, Inflammation, Chronic Active						1 (10%)
Renal Tubule, Regeneration	1 (10%)					1 (10%)
Transitional Epithelium, Hyperplasia	1 (10%)					1 (10%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)
Transitional Epithelium, Hyperplasia	1 (10%)					

*** END OF REPORT ***

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