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

Antimony trioxide CAS Number: 1309-64-4

First Da

Time Report Requested: 11:28:24

First Dose M/F: 10/06/08 / 10/06/08

Date Report Requested: 12/03/2014

Lab: BNW

Species/Strain: MICE/B6C3F1

Test Type: CHRONIC

F1\_53 Wk. SSAC\_M3

NTP Study Number: C20601

**Lock Date:** 06/22/2011

Cage Range: ALL

Route: RESPIRATORY EXPOSURE WHOLE BODY

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

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

Experiment Number: 20601 - 04

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE 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)	
Gallbladder	(8)	(10)	(9)	(9)	
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%)			
Clear Cell Focus	2 (20%)	2 (20%)	2 (20%)		
Mesentery	(0)	(0)	(0)	(1)	
Necrosis, Fatty				1 (100%)	
Pancreas	(10)	(10)	(10)	(10)	
Salivary Glands	(10)	(10)	(10)	(10)	
Stomach, Forestomach	(10)	(10)	(10)	(10)	
Stomach, Glandular	(10)	(9)	(10)	(10)	
Tooth	(1)	(0)	(0)	(0)	
Malformation	1 (100%)				
CARDIOVASCULAR SYSTEM					
Blood Vessel	(10)	(10)	(10)	(10)	
Heart	(10)	(10)	(10)	(10)	
Cardiomyopathy	, ,	,	,	1 (10%)	

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE MALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
ENDOCRINE SYSTEM					
Adrenal Cortex	(10)	(10)	(10)	(10)	
Zona Fasciculata, Hypertrophy	3 (30%)	1 (10%)		1 (10%)	
Adrenal Medulla	(10)	(10)	(10)	(10)	
Islets, Pancreatic	(10)	(10)	(10)	(10)	
Parathyroid Gland	(6)	(7)	(5)	(8)	
Pituitary Gland	(10)	(10)	(10)	(9)	
Thyroid Gland	(10)	(10)	(10)	(10)	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Epididymis	(10)	(10)	(10)	(10)	
Preputial Gland	(10)	(10)	(10)	(10)	
Inflammation, Chronic Active	1 (10%)	( - /	( - /	( - /	
Prostate	(10)	(10)	(10)	(10)	
Seminal Vesicle	(10)	(10)	(10)	(10)	
Testes	(10)	(10)	(10)	(10)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(10)	(10)	(10)	(10)	
Lymph Node, Bronchial	(8)	(10)	(10)	(10)	
Foreign Body	()	10 (100%)	10 (100%)	10 (100%)	
Hyperplasia, Lymphoid		7 (70%)	9 (90%)	10 (100%)	
Infiltration Cellular, Histiocyte		4 (40%)	4 (40%)	1 (10%)	
Lymph Node, Mandibular	(5)	(4)	(4)	(4)	
Infiltration Cellular, Histiocyte	(=)	( ' /	\ ·/	2 (50%)	
				= \/	

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

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

Experiment Number: 20601 - 04 Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE MALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
Lymph Node, Mediastinal	(4)	(8)	(10)	(10)	
Foreign Body		1 (13%)	8 (80%)	10 (100%)	
Hyperplasia, Lymphoid		1 (13%)	4 (40%)	9 (90%)	
Infiltration Cellular, Histiocyte		1 (13%)	3 (30%)	4 (40%)	
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	
Spleen	(10)	(10)	(10)	(10)	
Thymus	(10)	(10)	(10)	(10)	
Inflammation, Chronic Active				1 (10%)	
Medulla, Hyperplasia, Lymphoid		1 (10%)	1 (10%)		
INTEGUMENTARY SYSTEM					
Skin	(10)	(10)	(10)	(10)	
MUSCULOSKELETAL SYSTEM					
Bone	(10)	(10)	(10)	(10)	
NERVOUS SYSTEM					
Brain	(10)	(10)	(10)	(10)	
RESPIRATORY SYSTEM					
Larynx	(10)	(10)	(10)	(10)	
Foreign Body	` '	3 (30%)	5 (50%)	10 (100%)	
Respiratory Epithelium, Degeneration		,	1 (10%)	,	
Respiratory Epithelium, Hyperplasia		1 (10%)	4 (40%)	6 (60%)	
Respiratory Epithelium, Metaplasia, Squamous		, ,	2 (20%)	3 (30%)	
Lung	(10)	(10)	(10)	(10)	
Foreign Body		10 (100%)	10 (100%)	10 (100%)	
Infiltration Cellular, Lymphocyte		10 (100%)	10 (100%)	10 (100%)	
Inflammation, Chronic Active		10 (100%)	10 (100%)	10 (100%)	

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

Species/Strain: MICE/B6C3F1

Route: RESPIRATORY EXPOSURE WHOLE BODY

Test Type: CHRONIC

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

Antimony trioxide **CAS Number:** 1309-64-4 Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

Lab: BNW

86C3F1 MICE MALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
Alveolar Epithelium, Hyperplasia		9 (90%)	10 (100%)	10 (100%)	
Alveolar Epithelium, Metaplasia, Squamous				1 (10%)	
Alveolus, Fibrosis		4 (40%)	7 (70%)	10 (100%)	
Bronchiole, Epithelium, Hyperplasia		9 (90%)	9 (90%)	9 (90%)	
Pleura, Fibrosis		5 (50%)	10 (100%)	10 (100%)	
Pleura, Inflammation		7 (70%)	10 (100%)	10 (100%)	
Nose	(10)	(10)	(10)	(10)	
Foreign Body		8 (80%)	10 (100%)	9 (90%)	
Inflammation, Acute			1 (10%)		
Respiratory Epithelium, Accumulation, Hyaline Droplet	1 (10%)			1 (10%)	
Respiratory Epithelium, Inflammation, Chronic Active	1 (10%)				
Trachea	(10)	(10)	(10)	(10)	
Foreign Body			2 (20%)	4 (40%)	
Epithelium, Hyperplasia			1 (10%)		
Epithelium, Metaplasia, Squamous		1 (10%)		1 (10%)	
SPECIAL SENSES SYSTEM					
Eye	(10)	(10)	(10)	(10)	
Harderian Gland	(10)	(10)	(10)	(10)	
Hyperplasia	(1.5)	(/	()	1 (10%)	
JRINARY SYSTEM					
Kidney	(10)	(10)	(10)	(10)	
Nephropathy	2 (20%)	3 (30%)	4 (40%)	2 (20%)	
Glomerulus, Hyalinization	2 (2070)	0 (0070)	. (1070)	1 (10%)	
Papilla, Necrosis	1 (10%)			. (1070)	
Urinary Bladder	(10)	(10)	(10)	(10)	
Similary Diaddol	(10)	(10)	(10)	(10)	

# \*\*\* END OF MALE \*\*\*

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

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

Experiment Number: 20601 - 04

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE 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)	(10)	(10)	
Gallbladder	(10)	(10)	(10)	(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%)			
Clear Cell Focus			1 (10%)		
Pancreas	(10)	(10)	(10)	(10)	
Atrophy	, ,	, ,	1 (10%)	, ,	
Salivary Glands	(10)	(10)	(10)	(10)	
Stomach, Forestomach	(10)	(10)	(10)	(10)	
Stomach, Glandular	(10)	(10)	(10)	(10)	
Tooth	(1)	(0)	(0)	(0)	
Dysplasia	1 (100%)	,	, ,	, ,	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(10)	(9)	(10)	(10)	
Adventitia, Inflammation, Chronic Active	1 (10%)	(-)	( - /	( - /	
Heart	(10)	(10)	(10)	(10)	
Cardiomyopathy	( /	1 (10%)	(/	(,	

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE FEMALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
Artery, Inflammation, Chronic Active			1 (10%)		
ENDOCRINE SYSTEM					
Adrenal Cortex	(10)	(10)	(10)	(10)	
Adrenal Medulla	(10)	(10)	(10)	(10)	
Islets, Pancreatic	(10)	(10)	(10)	(10)	
Parathyroid Gland	(8)	(9)	(6)	(8)	
Pituitary Gland	(10)	(10)	(10)	(10)	
Thyroid Gland	(10)	(9)	(10)	(10)	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(10)	(9)	(7)	(7)	
Ovary	(10)	(10)	(10)	(10)	
Follicle, Cyst	1 (10%)		1 (10%)	1 (10%)	
Uterus	(10)	(10)	(10)	(10)	
Endometrium, Hyperplasia, Cystic	7 (70%)	9 (90%)	10 (100%)	9 (90%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(10)	(10)	(10)	(10)	
Lymph Node, Bronchial	(5)	(10)	(9)	(10)	
Foreign Body	. ,	10 (100%)	9 (100%)	10 (100%)	
Hyperplasia, Lymphoid		6 (60%)	9 (100%)	10 (100%)	
Infiltration Cellular, Histiocyte		1 (10%)	6 (67%)	4 (40%)	
Lymph Node, Mandibular	(6)	(8)	(7)	(8)	
Lymph Node, Mediastinal	(4)	(7)	(8)	(10)	
Foreign Body		2 (29%)	2 (25%)	9 (90%)	

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

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

Antimony trioxide CAS Number: 1309-64-4

Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE FEMALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
Hyperplasia, Lymphoid		1 (14%)	4 (50%)	4 (40%)	
Infiltration Cellular, Histiocyte			2 (25%)	3 (30%)	
Lymph Node, Mesenteric	(9)	(10)	(10)	(10)	
Spleen	(10)	(10)	(10)	(10)	
Hematopoietic Cell Proliferation			3 (30%)	2 (20%)	
Hyperplasia, Lymphoid		4 (40%)	6 (60%)	5 (50%)	
Thymus	(10)	(9)	(10)	(9)	
Medulla, Hyperplasia, Lymphoid	1 (10%)	4 (44%)	4 (40%)	3 (33%)	
INTEGUMENTARY SYSTEM					
Mammary Gland	(9)	(10)	(10)	(10)	
Skin	(10)	(10)	(10)	(10)	
Dermis, Infiltration Cellular, Mixed Cell	2 (20%)	1 (10%)	( - /	2 (20%)	
MUSCULOSKELETAL SYSTEM					
Bone	(10)	(10)	(10)	(10)	
Femur, Fibro-Osseous Lesion	1 (10%)	()	1 (10%)	(1-5)	
NERVOUS SYSTEM					
Brain	(10)	(10)	(10)	(10)	
RESPIRATORY SYSTEM					
Larynx	(10)	(9)	(10)	(10)	
Foreign Body	()	2 (22%)	7 (70%)	7 (70%)	
Respiratory Epithelium, Hyperplasia		1 (11%)	4 (40%)	. (. 5.5)	
Respiratory Epithelium, Metaplasia, Squamous	1 (10%)	- ( , • )	1 (10%)	8 (80%)	
Lung	(10)	(10)	(10)	(10)	
Foreign Body		10 (100%)	10 (100%)	10 (100%)	
Infiltration Cellular, Lymphocyte	3 (30%)	10 (100%)	10 (100%)	9 (90%)	

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

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

Antimony trioxide **CAS Number:** 1309-64-4 Date Report Requested: 12/03/2014 Time Report Requested: 11:28:24 First Dose M/F: 10/06/08 / 10/06/08

B6C3F1 MICE FEMALE	Control	3 mg/m3	10 mg/m3	30 mg/m3	
Inflammation, Chronic Active		10 (100%)	10 (100%)	10 (100%)	
Alveolar Epithelium, Hyperplasia		8 (80%)	10 (100%)	10 (100%)	
Alveolus, Fibrosis		2 (20%)	6 (60%)	10 (100%)	
Bronchiole, Epithelium, Hyperplasia		5 (50%)	10 (100%)	10 (100%)	
Pleura, Fibrosis		6 (60%)	9 (90%)	10 (100%)	
Pleura, Inflammation		7 (70%)	10 (100%)	10 (100%)	
Nose	(10)	(10)	(10)	(10)	
Foreign Body		6 (60%)	9 (90%)	10 (100%)	
Inflammation, Acute			1 (10%)		
Olfactory Epithelium, Accumulation, Hyaline Droplet	1 (10%)		, ,		
Olfactory Epithelium, Metaplasia, Respiratory				1 (10%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet	6 (60%)	4 (40%)	3 (30%)	, ,	
Respiratory Epithelium, Inflammation, Acute	1 (10%)				
Trachea	(10)	(10)	(10)	(10)	
Foreign Body			2 (20%)	4 (40%)	
Inflammation, Chronic Active		1 (10%)			
SPECIAL SENSES SYSTEM					
Eye	(10)	(10)	(10)	(10)	
Harderian Gland	(10)	(10)	(10)	(10)	
Hyperplasia	1 (10%)	()	(1-7)	(/	
URINARY SYSTEM					
Kidney	(10)	(10)	(10)	(10)	
Nephropathy	2 (20%)	(10)	1 (10%)	1 (10%)	
	, ,	(10)	` '		
Urinary Bladder	(10)	(10)	(10)	(10)	

<sup>\*\*\*</sup> END OF REPORT \*\*\*

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