Experiment Number: 05121-08 Test Type: CHRONIC Route: GAVAGE Species/Strain: Mouse/B6C3F1	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Test Compound: Scopolamine hydrobromide trihydrate CAS Number: 6533-68-2	Date Report Requested: 10/16/2014 Time Report Requested: 06:23:31 First Dose M/F: NA / NA Lab: BAT
C Number:	C03098C	
Lock Date:	05/13/1992	
Cage Range:	All	
Date Range:	All	
Reasons For Removal:	All	
Removal Date Range:	All	
Treatment Groups:	All	

Both

03/13/1995

Study Gender:

PWG Approval Date

Experiment Number: 05121-08 Test Type: CHRONIC

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:31

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:31 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Disposition Summary				
Animals Initially In Study	60	50	60	50
Scheduled Sacrifice	10		10	
Early Deaths				
Natural Death	1	2	2	1
Survivors				
Moribund Sacrifice		11		5
Natural Death		9		7
Terminal Sacrifice	49	28	48	37
Animals Examined Microscopically	60	50	60	50
ALIMENTARY SYSTEM				
Esophagus	(60)	(50)	(60)	(50)
Periesoph Tiss, Inflammation, Suppurative	1 [1.0]			
Gallbladder	(60)	(50)	(58)	(49)
Inflammation, Acute				1 [2.0]
Intestine Large, Cecum	(60)	(50)	(59)	(50)
Intestine Large, Colon	(60)	(50)	(60)	(49)
Intestine Large, Rectum	(59)	(50)	(59)	(50)
Intestine Small, Duodenum	(60)	(50)	(59)	(50)
Intestine Small, Ileum	(59)	(50)	(60)	(49)
Intestine Small, Jejunum	(60)	(50)	(60)	(49)
Hyperplasia, Lymphoid	1 [4.0]	1 [3.0]	1 [2.0]	5 [3.2]
Inflammation, Chronic Active		1 [4.0]		
Liver	(60)	(50)	(60)	(50)
Basophilic Focus		1		1
Bile Duct, Cyst				2
Bile Duct, Hyperplasia, Cystic	1 [2.0]			
Clear Cell Focus	1			

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

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Eosinophilic Focus	1	1	·	1
Hematopoietic Cell Proliferation		1 [1.0]		
Hepatodiaphragmatic Nodule		1 [2.0]		
Hyperplasia, Lymphoid		2 [1.5]		
Mixed Cell Focus		2	1	
Necrosis	1 [1.0]	1 [2.0]	1 [1.0]	
Mesentery	(1)	(5)	(0)	(1)
Artery, Inflammation, Chronic Active				1 [2.0]
Fat, Inflammation, Chronic Active		3 [3.0]		
Fat, Necrosis		2 [3.0]		
Fibrosis	1 [2.0]			
Pancreas	(60)	(50)	(60)	(50)
Acinus, Atrophy		2 [2.5]	1 [1.0]	
Acinus, Hyperplasia, Focal				1 [1.0]
Artery, Inflammation, Chronic Active		2 [2.0]		
Duct, Ectasia		1 [3.0]		
Inflammation, Chronic Active		1 [2.0]		
Salivary Glands	(60)	(50)	(60)	(50)
Stomach, Forestomach	(60)	(50)	(60)	(50)
Cyst				2
Hyperplasia, Focal	44 [1.8]	25 [2.2]	38 [2.0]	33 [1.9]
Hyperplasia, Mast Cell				3 [1.7]
Stomach, Glandular	(60)	(50)	(60)	(50)
Dysplasia	1 [2.0]	1 [2.0]	2 [1.5]	3 [2.0]
Hyperplasia		1 [3.0]		
Tongue	(1)	(0)	(0)	(1)
Mineralization	1 [2.0]			
Tooth	(2)	(3)	(0)	(7)
Dysplasia	2 [1.0]	3 [2.0]		6 [2.5]

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

Test Type: CHRONIC Route: GAVAGE

Species/Strain: Mouse/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 10/10/201 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Inflammation, Chronic Active			· · · · · · · · · · · · · · · · · · ·	1 [2.0]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(60)	(50)	(60)	(50)
Heart	(60)	(50)	(60)	(50)
Atrium, Thrombosis				1 [3.0]
Degeneration		1 [3.0]		
Inflammation, Chronic Active	1 [1.0]			
Mineralization		1 [1.0]		1 [1.0]
Valve, Inflammation, Chronic Active				1 [2.0]
ENDOCRINE SYSTEM				
Adrenal Cortex	(60)	(50)	(60)	(50)
Accessory Adrenal Cortical Nodule	4 [1.5]	1 [1.0]		1 [1.0]
Capsule, Hyperplasia		3 [2.7]		1 [3.0]
Capsule, Hyperplasia, Adenomatous	6 [1.3]			
Hematopoietic Cell Proliferation		1 [1.0]		
Hemorrhage		1 [2.0]		
Hyperplasia	14 [1.1]	6 [1.8]	6 [1.0]	12 [1.4]
Adrenal Medulla	(60)	(50)	(59)	(50)
Hyperplasia		3 [2.7]		1 [1.0]
Islets, Pancreatic	(60)	(50)	(59)	(50)
Hyperplasia	1 [1.0]	3 [1.0]		
Parathyroid Gland	(49)	(50)	(54)	(47)
Cyst				1
Hyperplasia, Focal				1 [2.0]
Pituitary Gland	(58)	(47)	(38)	(47)
Cyst			1	
Pars Distalis, Cyst		3		1
Pars Distalis, Hyperplasia		2 [1.0]		3 [1.3]

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

Species/Strain: Mouse/B6C3F1

Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 10/10/201 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Thyroid Gland	(60)	(50)	(60)	(50)
Follicular Cel, Hyperplasia	1 [2.0]	6 [1.2]		2 [2.0]
Inflammation		1 [1.0]		
Inflammation, Chronic Active				1 [2.0]
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(0)	(1)
GENITAL SYSTEM				
Epididymis	(60)	(50)	(60)	(50)
Granuloma Sperm		7 [2.0]		6 [1.3]
Inflammation, Chronic Active		1 [3.0]		
Spermatocele				1
Preputial Gland	(60)	(50)	(59)	(50)
Degeneration				1 [3.0]
Duct, Ectasia	24 [3.3]	24 [2.9]	10 [2.7]	15 [2.4]
Inflammation, Chronic Active	2 [2.5]	7 [3.3]	1 [4.0]	6 [3.2]
Prostate	(60)	(50)	(60)	(50)
Seminal Vesicle	(60)	(50)	(60)	(50)
Testes	(60)	(50)	(60)	(50)
Atrophy	1 [2.0]	9 [2.0]		7 [1.6]
Hypoplasia	1 [4.0]			
Interstit Cell, Hyperplasia		1 [2.0]		
HEMATOPOIETIC SYSTEM				
Bone Marrow	(60)	(50)	(60)	(50)
Erythroid Cell, Hyperplasia		. ,		3 [3.0]
Hyperplasia, Mast Cell	1 [1.0]			
Myelofibrosis		2 [1.0]		
Myeloid Cell, Hyperplasia		6 [2.8]		1 [1.0]
Lymph Node	(0)	(4)	(0)	(4)

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

Test Type: CHRONIC

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Lymph Node, Bronchial	(0)	(0)	(3)	(0)
Lymph Node, Mandibular	(60)	(48)	(59)	(47)
Hyperplasia, Lymphoid				1 [3.0]
Lymph Node, Mediastinal	(1)	(7)	(0)	(3)
Lymph Node, Mesenteric	(60)	(49)	(59)	(46)
Angiectasis		5 [2.6]		5 [2.8]
Hyperplasia, Lymphoid				2 [4.0]
Hyperplasia, Plasma Cell				1 [2.0]
Spleen	(60)	(50)	(60)	(50)
Depletion Lymphoid		2 [3.5]	1 [1.0]	1 [2.0]
Hematopoietic Cell Proliferation	2 [2.0]	15 [2.3]	1 [2.0]	11 [2.1]
Hyperplasia, Lymphoid		1 [1.0]		1 [2.0]
Hyperplasia, Plasma Cell				1 [2.0]
Thrombosis		1 [3.0]		
Thymus	(55)	(34)	(55)	(38)
Atrophy		13 [3.2]	1 [3.0]	9 [2.4]
INTEGUMENTARY SYSTEM				
Mammary Gland	(1)	(0)	(0)	(0)
Skin	(60)	(48)	(60)	(50)
Subcut Tiss, Inflammation, Chronic Active		2 [2.0]		
MUSCULOSKELETAL SYSTEM				
Bone	(60)	(50)	(60)	(50)
Skeletal Muscle	(0)	(0)	(0)	(1)
NERVOUS SYSTEM				
Brain	(60)	(50)	(60)	(50)
Infiltration Cellular, Lymphocyte	. /	. /	1 [2.0]	. ,
Peripheral Nerve	(0)	(1)	(0)	(1)
Spinal Cord	(0)	(1)	(0)	(1)

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

Experiment Number: 05121-08 Test Type: CHRONIC

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 10/10/201 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
RESPIRATORY SYSTEM				
Lung	(60)	(50)	(60)	(50)
Alveolar Epith, Hyperplasia	5 [1.6]	4 [1.5]	1 [1.0]	7 [2.1]
Bronchiectasis, Focal	1 [2.0]			
Bronchiole, Hyperplasia		1 [2.0]	1 [1.0]	
Inflammation		1 [1.0]		
Nose	(60)	(50)	(60)	(50)
Respirat Epith, Inflammation, Chronic Active	1 [2.0]			
Trachea	(60)	(50)	(60)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(2)	(0)	(0)
Eye	(0)	(1)	(0)	(3)
Lens, Cataract		1 [1.0]		2 [1.0]
Harderian Gland	(26)	(24)	(26)	(23)
Hyperplasia	1 [3.0]			
Inflammation, Chronic Active	2 [2.5]		2 [2.5]	
URINARY SYSTEM				
Kidney	(60)	(50)	(60)	(50)
Cyst		3 [2.0]		1
Hyperplasia, Mast Cell	1 [1.0]			
Necrosis, Focal		1 [2.0]		
Nephropathy	56 [1.0]	40 [1.1]	50 [1.0]	40 [1.1]
Renal Tubule, Hyperplasia	1 [1.0]			1 [1.0]
Urinary Bladder	(60)	(50)	(59)	(49)

END OF MALE DATA

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

Experiment Number: 05121-08
Test Type: CHRONIC
Route: GAVAGE

Species/Strain: Mouse/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 10/10/201 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Disposition Summary				
Animals Initially In Study	60	50	60	50
Scheduled Sacrifice	10		10	
Early Deaths				
Dosing Accident			1	
Moribund Sacrifice	2	4	2	3
Natural Death	1	1	3	2
Survivors				
Dosing Accident				1
Moribund Sacrifice		14		13
Natural Death		11		12
Terminal Sacrifice	47	20	44	19
Animals Examined Microscopically	60	50	60	50
ALIMENTARY SYSTEM				
Esophagus	(59)	(50)	(60)	(50)
Periesoph Tiss, Degeneration			1 [3.0]	
Periesoph Tiss, Hemorrhage				1 [4.0]
Gallbladder	(60)	(50)	(60)	(49)
Inflammation, Chronic Active		1 [2.0]		1 [2.0]
Intestine Large, Cecum	(60)	(49)	(60)	(48)
Intestine Large, Colon	(60)	(49)	(60)	(50)
Intestine Large, Rectum	(60)	(50)	(60)	(49)
Intestine Small, Duodenum	(60)	(50)	(60)	(50)
Intestine Small, Ileum	(57)	(49)	(60)	(50)
Intestine Small, Jejunum	(60)	(50)	(60)	(49)
Hemorrhage				1 [2.0]
Hyperplasia, Lymphoid		1 [1.0]		
Liver	(60)	(50)	(60)	(50)

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

Test Type: CHRONIC Route: GAVAGE

Species/Strain: Mouse/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 10/10/201 First Dose M/F: NA / NA Lab: BAT

Angiectasis 1 [2.0] 1 [1.0] Basophilic Focus 1 2 3 Bile Duct, Cyst 2 3 Bile Duct, Hyperplasia 1 [2.0] 2 Centribular, Necrosis 1 [3.0] 2 Clear Cell Focus 2 2 Eosinophilic Focus 4 1 Hematopoietic Cell Proliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 1 [2.0] Inflammation, Focal 1 [2.0] 1 Mecrosis 2 1 1 Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (43) 3 [3.3] 3 [3.7] Acinus, Atrophy 2 [3.0] 2 1 1 Duct, Ectasia 1 [4.0] 1 [4.0] 2 [4.0] 5 Salivary Glands (60) (50) (50) 5 5 Stomach, Forestomach (60) (50)<	B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Bile Duct, Cyst 1[2.0] Bile Duct, Hyperplasia 1[2.0] Centrilobular, Necrosis 1[3.0] Clear Cell Focus 2 Eosinophilic Focus 4 1 Hematopoietic Cell Proliferation 1[1.0] 2[2.0] Hyperplasia, Lymphoid 1[1.0] 2[2.0] Hyperplasia, Lymphoid 1[1.0] 2[2.0] Mixed Cell Focus 2 1 Necrosis 2[1.0] 1[1.0] 1[2.0] Serosa, Pigmentation, Hemosiderin 1[1.0] 1[2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 2[3.0] 2[3.3] 3[3.7] Acinus, Hyperplasia, Focal 3[1.0] 2[4.0] 3[4.0] Artery, Inflammation, Chronic Active 2[3.0] 500 (50) Stomach, Forestomach (60) (49) (60) (50) Stomach, Geradu AS 36[1.7] 23[2.0] 37[1.8] 29[1.8] Infiltration 1[2.0] 1[2.0] 1[2.0] 500	Angiectasis	1 [2.0]			1 [1.0]
Bile Duct, Hyperplasia 1 [2.0] Centrilobular, Necrosis 1 [3.0] Clear Cell Focus 2 Eosinophilic Focus 4 1 Hematopoietic Cell Proliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 1 Inflammation, Focal 1 [2.0] 1 Necrosis 2 1 1.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 12.0] Serosa, Pigmentation, Chronic Active 2 [3.0] 3 [3.3] 3 [3.7] Acinus, Atrophy 3 [3.0] 3 [3.7] 3 [3.7] Acinus, Atrophy 2 [3.0] 1 [4.0] 2 [4.0] Duct, Ectasia 660) (49) (60) (50) Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (49) (60) (50) Stomach, Forestomach (60) (49) (60) (50) Stomach, Forestomach 1 [1.0] 1 1 1 Hyperplasia, Focal <td< td=""><td>Basophilic Focus</td><td>1</td><td></td><td>2</td><td>3</td></td<>	Basophilic Focus	1		2	3
Centrilobular, Necrosis 1 [3.0] Clear Cell Focus 2 Eosinophilic Focus 4 1 Hematopoietic Cell Poliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 2 [2.0] Inflammation, Focal 1 [2.0] 1 Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0]	Bile Duct, Cyst				2
Clear Cell Focus 4 1 Eosinophilic Focus 4 1 Hematopoietic Cell Proliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 2 [2.0] Inflammation, Focal 1 [2.0] 1 Mixed Cell Focus 2 1 Necrosis 2 1 Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] Mesentery (2) (6) (0) (6) Pancreas (60) (49) (50) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0]	Bile Duct, Hyperplasia			1 [2.0]	
Eosinophilic Focus 4 1 Hematopoietic Cell Proliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 2 [2.0] Inflammation, Focal 1 [2.0] 1 Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 2 [3.0] 2 [4.0] 2 [4.0] Salivary Glands (60) (49) (60) (50) Salivary Glands (60) (49) (60) (50) Salivary Glands (60) (50) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1 1 2 9 1.8] Herey Inflammation, Cellular, Mast Cell 1 2 3 1 1 1	Centrilobular, Necrosis	1 [3.0]			
Herratopoletic Cell Proliferation 1 [1.0] 2 [2.0] Hyperplasia, Lymphoid 1 [1.0] 1 Inflammation, Focal 1 [2.0] 1 Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0] 1 1 1 Actinus, Hyperplasia, Focal 3 [1.0] 1 2 [4.0] 50) Salivary Glands (60) (49) (60) (50) Surger Glands (60) (50) (60) (50) Cyst 1 1 2 29 [1.8] Inflitation Cellular, Mast Cell 1 [2.0] 1 29 [1.8] Inflitation Cellular, Mast Cell 1 [2.0] 1 1 1	Clear Cell Focus				2
Hyperplasia, Lymphoid 1 [1.0] Inflammation, Focal 1 [2.0] Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 [2.0] Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0] 4 [3.6] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0] 2 [3.0] 2 [4.0] Salivary Glands (60) (49) (60) (50) Suivary Glands (60) (50) (60) (50) Cyst 1 [4.0] 1 [4.0] 2 [4.0] Erosion 1 [1.0] 1 1 Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization	Eosinophilic Focus		4	1	
Inflammation, Focal 1 [2.0] Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 3 [3.0] 3 [3.7] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0]	Hematopoietic Cell Proliferation		1 [1.0]		2 [2.0]
Mixed Cell Focus 2 1 Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0] 1 [2.0] 1 Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0]	Hyperplasia, Lymphoid	1 [1.0]			
Necrosis 2 [1.0] 1 [1.0] 1 [2.0] Serosa, Pigmentation, Hemosiderin 1 [1.0]	Inflammation, Focal		1 [2.0]		
Serosa, Pigmentation, Hemosiderin 1 [1.0] Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Atrophy 2 [3.0] 7 Artery, Inflammation, Chronic Active 2 [3.0] 7 Duct, Ectasia (60) (49) (60) (50) Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1 1 2 2 9 1.8] Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization (60) (50) (60) (50) 1 Stomach, Glandular (60) (50) 1 1 2.0]	Mixed Cell Focus	2			1
Mesentery (2) (6) (0) (6) Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0] 2 [3.0]	Necrosis		2 [1.0]	1 [1.0]	1 [2.0]
Pancreas (60) (49) (60) (50) Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0] 3 3 Actrey, Inflammation, Chronic Active 2 [3.0] 1 2 [4.0] Duct, Ectasia 660) (49) (60) (50) Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1 1 1 2 [4.0] Hyperplasia, Focal 36 [0.7] 23 [2.0] 37 [1.8] 2 [4.0] Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization 1 1 1 1 1 Stomach, Glandular (60) (50) (60) (50) 1 Dysplasia 1 1 1 1 1 1 1	Serosa, Pigmentation, Hemosiderin	1 [1.0]			
Acinus, Atrophy 4 [3.5] 3 [3.3] 3 [3.7] Acinus, Hyperplasia, Focal 3 [1.0]	Mesentery	(2)	(6)	(0)	(6)
Acinus, Hyperplasia, Focal 3 [1.0] Artery, Inflammation, Chronic Active 2 [3.0] Duct, Ectasia 1 [4.0] 1 [4.0] 2 [4.0] Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (50) (50) Cyst 1 1 1 1 1 Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization 1 1 1 1 1 1 Stomach, Glandular (60) (50) (60) (50) 1	Pancreas	(60)	(49)	(60)	(50)
Artery, Inflammation, Chronic Active 2 [3.0] Duct, Ectasia 1 [4.0] 1 [4.0] 2 [4.0] Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1 1 1 1 1 Erosion 1 [1.0] 1 29 [1.8] 1 Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Stomach, Glandular (60) (50) (60) (50) 1 Dysplasia 1 2.0] 1 1 1 1	Acinus, Atrophy		4 [3.5]	3 [3.3]	3 [3.7]
Duct, Ectasia 1 [4.0] 1 [4.0] 2 [4.0] Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1 1 1 1 Erosion 1 [1.0] 1 29 [1.8] 1 Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization (60) (50) (60) (50) 1 Stomach, Glandular (60) (50) (60) (50) 1 Dysplasia 1 1 1 1 1 1	Acinus, Hyperplasia, Focal	3 [1.0]			
Salivary Glands (60) (49) (60) (50) Stomach, Forestomach (60) (50) (60) (50) Cyst 1	Artery, Inflammation, Chronic Active		2 [3.0]		
Stomach, Forestomach (60) (50) (60) (50) Cyst 1	Duct, Ectasia		1 [4.0]	1 [4.0]	2 [4.0]
Cyst 1 Erosion 1 [1.0] Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization 1 1 1 1 1 Stomach, Glandular (60) (50) (60) (50) Dysplasia 1 1 1 1	Salivary Glands	(60)	(49)	(60)	(50)
Erosion 1 [1.0] Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 1 1 Mineralization 1 (60) (50) (60) (50) Stomach, Glandular (60) (50) (60) 1 [2.0]	Stomach, Forestomach	(60)	(50)	(60)	(50)
Hyperplasia, Focal 36 [1.7] 23 [2.0] 37 [1.8] 29 [1.8] Infiltration Cellular, Mast Cell 1 [2.0] 1 </td <td>Cyst</td> <td></td> <td>1</td> <td></td> <td></td>	Cyst		1		
Infiltration Cellular, Mast Cell1 [2.0]Mineralization1 [2.0]Stomach, Glandular(60)Dysplasia(50)1 [2.0]	Erosion	1 [1.0]			
Mineralization1 [2.0]Stomach, Glandular(60)(50)(60)(50)Dysplasia1 [2.0]1 [2.0]	Hyperplasia, Focal	36 [1.7]	23 [2.0]	37 [1.8]	29 [1.8]
Stomach, Glandular (60) (50) (60) (50) Dysplasia 1 [2.0]	Infiltration Cellular, Mast Cell	1 [2.0]			
Dysplasia 1 [2.0]	Mineralization				1 [2.0]
	Stomach, Glandular	(60)	(50)	(60)	(50)
Erosion 1 [1 0]	Dysplasia				1 [2.0]
	Erosion				1 [1.0]

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

Test Type: CHRONIC

Route: GAVAGE Species/Strain: Mouse/B6C3F1

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Mineralization				1 [2.0]
Tooth	(0)	(2)	(0)	(2)
Dysplasia		2 [4.0]		1 [1.0]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(60)	(50)	(60)	(50)
Aorta, Inflammation		1 [4.0]		
Aorta, Thrombosis		2 [4.0]		
Inflammation, Chronic Active			1 [2.0]	
Heart	(60)	(50)	(60)	(50)
Degeneration				1 [1.0]
Inflammation, Chronic Active	1 [1.0]			
Mineralization	2 [1.0]	1 [1.0]		
ENDOCRINE SYSTEM				
Adrenal Cortex	(59)	(50)	(60)	(50)
Accessory Adrenal Cortical Nodule	1		1 [2.0]	1 [1.0]
Angiectasis		1 [2.0]		2 [3.0]
Capsule, Hyperplasia		1 [3.0]		
Hyperplasia	2 [1.5]	2 [1.5]	1 [3.0]	2 [1.5]
Hypertrophy	1 [3.0]			
Adrenal Medulla	(59)	(49)	(60)	(50)
Hyperplasia				1 [4.0]
Islets, Pancreatic	(60)	(49)	(60)	(50)
Hyperplasia		1 [1.0]		
Parathyroid Gland	(52)	(45)	(49)	(46)
Cyst			2	1
Pituitary Gland	(56)	(42)	(56)	(49)
Pars Distalis, Hyperplasia	2 [1.0]	8 [2.1]	4 [1.5]	1 [2.0]
Pars Intermed, Hyperplasia	1 [1.0]			

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

Test Type: CHRONIC

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Thyroid Gland	(60)	(50)	(59)	(50)
Follicular Cel, Hyperplasia	2 [1.0]	9 [1.4]		2 [2.0]
Inflammation, Chronic Active	1 [1.0]			
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(1)	(0)
GENITAL SYSTEM				
Clitoral Gland	(59)	(50)	(59)	(48)
Duct, Ectasia	、 <i>、</i>	2 [1.5]	. ,	. ,
Inflammation, Chronic Active		1 [3.0]		1 [3.0]
Ovary	(60) (49) (60)		(49)	
Angiectasis		2 [3.0]	1 [2.0]	1 [3.0]
Atrophy	1 [2.0]			
Corpus Luteum, Hyperplasia		1 [3.0]		
Cyst	14 [1.7]	18	9 [1.7]	19
Hemorrhage	1 [4.0]			
Inflammation, Chronic Active		2 [4.0]		
Thrombosis		1 [3.0]		1 [3.0]
Uterus	(60)	(49)	(60)	(49)
Hemorrhage		1 [4.0]		
Hyperplasia, Cystic	16 [1.3]	9 [1.2]	17 [1.1]	11 [1.7]
Inflammation, Suppurative	1 [2.0]			
Thrombosis		1 [4.0]		
HEMATOPOIETIC SYSTEM				
Blood	(0)	(0)	(0)	(1)
Bone Marrow	(60)	(50)	(60)	(50)
Angiectasis	、 <i>、</i>	1 [4.0]	、 <i>,</i>	. ,
Erythroid Cell, Hyperplasia		4 [2.5]	1 [2.0]	1 [4.0]
Myelofibrosis	7 [1.6]	19 [1.5]	13 [1.2]	13 [1.3]

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

Species/Strain: Mouse/B6C3F1

Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Myeloid Cell, Hyperplasia	1 [3.0]	9 [2.6]	1 [2.0]	7 [3.4]
Lymph Node	(0)	(13)	(0)	(8)
Hematopoietic Cell Proliferation				1 [3.0]
Hyperplasia, Lymphoid		1 [4.0]		
Lymph Node, Bronchial	(0)	(0)	(1)	(1)
Lymph Node, Mandibular	(60)	(45)	(58)	(47)
Hematopoietic Cell Proliferation				1 [3.0]
Hyperplasia, Lymphoid	1 [3.0]	1 [3.0]	1 [4.0]	
Lymph Node, Mediastinal	(2)	(12)	(4)	(11)
Lymph Node, Mesenteric	(51)	(43)	(60)	(48)
Angiectasis		3 [1.3]		1 [3.0]
Hyperplasia, Lymphoid			1 [4.0]	
Spleen	(60)	(50)	(60)	(50)
Depletion Lymphoid				1 [2.0]
Hematopoietic Cell Proliferation	3 [4.0]	21 [2.9]	7 [2.0]	17 [2.9]
Hyperplasia, Lymphoid	1 [2.0]	2 [2.5]		
Thymus	(55)	(37)	(59)	(42)
Atrophy	1 [2.0]	9 [3.1]	1 [4.0]	5 [2.8]
Hyperplasia, Lymphoid			2 [3.5]	
INTEGUMENTARY SYSTEM				
Mammary Gland	(60)	(49)	(60)	(49)
Hyperplasia		1 [2.0]		
Skin	(60)	(50)	(60)	(50)
Subcut Tiss, Inflammation, Chronic Active		1 [4.0]		1 [3.0]
MUSCULOSKELETAL SYSTEM				
Bone	(60)	(50)	(60)	(50)
Skeletal Muscle	(2)	(0)	(0)	(0)

NERVOUS SYSTEM

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

Test Type: CHRONIC

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 06:23:32

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M	
Brain	(60)	(50)	(60)	(50)	
Granuloma, Focal				1 [2.0]	
Neuron, Necrosis		1 [1.0]			
Peripheral Nerve	(0)	(1)	(3) (1)	(0) (0)	
Spinal Cord	(0)	(1)			
RESPIRATORY SYSTEM					
Lung	(60) (50)		(60)	(50)	
Alveolar Epith, Hyperplasia	1 [1.0]		4 [1.0]	4 [1.0]	
Infiltration Cellular, Histiocyte	2 [2.5]				
Infiltration Cellular, Lymphocyte		1 [2.0]			
Inflammation, Chronic Active		(50)	1 [1.0] (59)	1 [1.0] (50)	
Nose	(60)				
Infiltration Cellular, Mast Cell		1 [4.0]			
Trachea	(60)	(50)	(59)	(50)	
SPECIAL SENSES SYSTEM					
Ear	(0)	(1)	(1)	(1)	
Eye	(0)	(1)	(0)	(3)	
Lens, Cataract		(0) (1) (0) 1 [1.0]		3 [1.3]	
Harderian Gland	(24)	(22)	(26)	(25)	
Hyperplasia				1 [2.0]	
Inflammation, Chronic Active			1 [2.0]		
URINARY SYSTEM					
Kidney	(60)	(50)	(60)	(50)	
Cytoplasmic Alteration		1 [4.0]	1 [2.0]		
Infiltration Cellular, Lymphocyte		1 [2.0]			
Nephropathy	16 [1.0]	19 [1.1]	6 [1.0]	13 [1.1]	
Pelvis, Inflammation, Chronic Active				1 [2.0]	
Renal Tubule, Necrosis	1 [3.0]				

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

Experiment Number: 05121-08 Test Type: CHRONIC Route: GAVAGE Species/Strain: Mouse/B6C3F1	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Test Compound: Scopolamine hydrobromide trihydrate CAS Number: 6533-68-2			Date Report Requested: 10/16/2014 Time Report Requested: 06:23:32 First Dose M/F: NA / NA Lab: BAT	
B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M	
Urinary Bladder	(60)	(49)	(60)	(49)	
Inflammation, Chronic Active		1 [3.0]		1 [2.0]	

** END OF REPORT **

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