Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 **AVERAGE SEVERITY GRADES[b]**

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

F2_M3

C Number: C99037B

Lock Date: 11/20/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25022 ACCK 25021 TSAC 25020 NATD

> 25019 MSAC 25018 DACC

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.2.0

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Disposition Summary						
Animals Initially In Study	50	50	50	50	50	
Early Deaths						
Dosing Accident		1				
Moribund Sacrifice	3		4	4		
Natural Death	7	7	5	9	36	
Survivors						
Natural Death					1	
Terminal Sacrifice	40	42	41	37	13	
Animals Examined Microscopically	50	50	50	50	50	
ALIMENTARY SYSTEM						
Esophagus	(50)	(50)	(50)	(49)	(50)	
Inflammation, Acute		1 [3.0]				
Ulcer		1 [4.0]				
Submucosa, Edema		1 [2.0]				
Intestine Small, Duodenum	(48)	(46)	(50)	(46)	(48)	
Ulcer				1 [2.0]		
Intestine Small, Ileum	(50)	(48)	(48)	(47)	(49)	
Epithelium, Hyperplasia		1 [3.0]				
Intestine Small, Jejunum	(48)	(46)	(49)	(46)	(43)	
Inflammation, Chronic Active				1 [3.0]		
Liver	(50)	(50)	(50)	(50)	(50)	
Basophilic Focus	2	1		5	2	
Clear Cell Focus	17	14	13	21	6	
Cyst		1 [3.0]				
Eosinophilic Focus	2	5	5	5		
Eosinophilic Focus, Multiple			1			
Hematopoietic Cell Proliferation	1 [1.0]			1 [4.0]		
Hemorrhage				1 [2.0]		
Inflammation, Chronic					1 [3.0]	
Inflammation, Chronic Active	2 [1.5]	1 [3.0]	3 [2.3]	3 [3.0]	1 [1.0]	
Mixed Cell Focus	12	7	11	7	3	
Necrosis, Focal	4 [3.0]		5 [2.0]	3 [2.3]	3 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Necrosis, Diffuse	1 [2.0]			1 [3.0]	1 [4.0]	
Tension Lipidosis			1			
Centrilobular, Necrosis		2 [2.5]	1 [3.0]			
Hepatocyte, Hypertrophy					1 [2.0]	
Hepatocyte, Vacuolization Cytoplasmic	23 [3.0]	13 [2.7]	20 [3.0]	17 [2.8]	5 [3.0]	
Kupffer Cell, Hyperplasia			1 [3.0]			
Kupffer Cell, Pigmentation				1 [3.0]		
Mesentery	(4)	(4)	(3)	(7)	(3)	
Fat, Necrosis	3 [2.3]	3 [4.0]	2 [3.0]	6 [2.7]	3 [2.7]	
Pancreas	(50)	(50)	(50)	(50)	(50)	
Atrophy		3 [2.7]	1 [1.0]	2 [2.5]	1 [1.0]	
Basophilic Focus			2			
Acinus, Cytoplasmic Alteration	2 [3.0]	6 [2.8]	3 [3.0]	1 [3.0]		
Acinus, Hyperplasia, Focal	1 [1.0]		1 [1.0]			
Salivary Glands	(50)	(50)	(50)	(50)	(50)	
Infiltration Cellular, Lymphocyte	3 [3.0]	10 [2.6]	4 [2.3]	3 [2.3]	1 [2.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)	
Diverticulum		1				
Inflammation, Chronic	4 [1.8]	5 [1.8]	3 [2.7]	3 [1.3]	2 [3.0]	
Ulcer	1 [2.0]	1 [2.0]				
Epithelium, Hyperplasia	7 [2.6]	7 [2.6]	8 [2.8]	3 [2.0]	5 [2.6]	
Stomach, Glandular	(50)	(50)	(50)	(49)	(50)	
Cyst	1 [3.0]	3 [3.0]	1 [3.0]			
Erosion	2 [1.5]	1 [2.0]	1 [3.0]	1 [2.0]		
Epithelium, Hyperplasia	1 [2.0]		1 [3.0]		1 [2.0]	
Epithelium, Metaplasia, Squamous				1 [1.0]		
Tongue	(1)	(0)	(0)	(1)	(0)	
CARDIOVASCULAR SYSTEM		,				
Heart	(50)	(50)	(50)	(50)	(50)	
Cardiomyopathy	(00)	2 [1.0]	(30)	1 [1.0]	(00)	
Inflammation, Chronic Active		2 [1.0]		1 [2.0]		
Mineralization	1 [1.0]			، رح.۰۰		
Thrombosis	1 [4.0]					
THOMBOOK	رح.ن					

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
ENDOCRINE SYSTEM						
Adrenal Cortex	(50)	(50)	(50)	(50)	(50)	
Accessory Adrenal Cortical Nodule	4 [3.0]	5 [3.0]	7 [3.0]	2 [3.0]	4 [3.0]	
Cyst	. [0.0]	0 [0.0]	, [0.0]	2 [0.0]	1 [1.0]	
Degeneration, Fatty		1 [2.0]			1 [1.0]	
Hyperplasia, Focal	5 [1.6]	7 [1.7]	5 [2.0]	2 [1.0]	1 [3.0]	
Hypertrophy, Focal	16 [1.3]	20 [1.9]	20 [1.5]	14 [1.4]	2 [1.5]	
Subcapsular, Hyperplasia	11 [2.4]	7 [2.1]	4 [2.5]	7 [2.1]	4 [2.0]	
Adrenal Medulla	(49)	(49)	(50)	(50)	(50)	
Hyperplasia	(12)	2 [1.5]	1 [2.0]	()	()	
Islets, Pancreatic	(50)	(50)	(50)	(50)	(50)	
Atrophy	(00)	(00)	(00)	1 [4.0]	(00)	
Hyperplasia	12 [2.3]	8 [2.0]	12 [1.7]	10 [1.8]	3 [1.3]	
Parathyroid Gland	(43)	(48)	(47)	(46)	(48)	
Cyst	(10)	(10)	(,	4 [3.0]	(13)	
Pituitary Gland	(48)	(50)	(48)	(49)	(49)	
Pars Distalis, Cyst	4 [3.0]	3 [3.0]	2 [3.0]	2 [3.0]	(10)	
Pars Distalis, Hyperplasia, Focal	1 [1.0]	2 [1.0]	1 [1.0]	2 [0.0]		
Rathke's Cleft, Dilatation	. [0]	2 [0]	. [0]		2 [1.0]	
Thyroid Gland	(49)	(50)	(50)	(49)	(50)	
Follicle, Cyst	(10)	(00)	(00)	1 [3.0]	(66)	
Follicle, Degeneration, Focal	13 [1.5]	10 [1.7]	11 [1.8]	16 [1.8]	6 [1.3]	
Follicular Cell, Hyperplasia		1 [2.0]	[0]		0 [0]	
GENERAL BODY SYSTEM						
Tissue NOS	(1)	(1)	(1)	(1)	(0)	
GENITAL SYSTEM						
Epididymis Granuloma Sperm	(50)	(50) 2 [3.0]	(50)	(50)	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57
First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Inflammation, Chronic				1 [2.0]		
Spermatocele		1 [2.0]				
Penis	(1)	(0)	(0)	(1)	(0)	
Cyst	()	()	()	1 [3.0]	,	
Preputial Gland	(49)	(49)	(50)	(50)	(50)	
Cyst	12 [3.0]	15 [3.0]	7 [3.0]	17 [3.0]	3 [3.0]	
Inflammation, Chronic	13 [2.5]	11 [2.4]	10 [2.6]	10 [2.3]	5 [2.4]	
Prostate	(49)	(50)	(50)	(50)	(50)	
Infiltration Cellular, Lymphocyte	. ,	, ,	1 [3.0]	, ,	, ,	
Seminal Vesicle	(50)	(50)	(50)	(50)	(50)	
Testes	(50)	(50)	(50)	(50)	(50)	
Angiectasis		1 [3.0]				
Germinal Epithelium, Atrophy		4 [2.0]	2 [1.0]	1 [2.0]		
Interstitial Cell, Hyperplasia		-	1 [3.0]	-		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(50)	(50)	(50)	(50)	(50)	
Hyperplasia	23 [2.5]	25 [2.4]	23 [2.5]	21 [2.8]	7 [2.7]	
Lymph Node	(3)	(0)	(1)	(1)	(0)	
Lymph Node, Mandibular	(47)	(49)	(46)	(47)	(44)	
Atrophy	1 [3.0]	1 [3.0]	1 [2.0]			
Hemorrhage				1 [2.0]		
Hyperplasia, Lymphoid	5 [2.2]	1 [2.0]	9 [1.9]	5 [1.8]	1 [2.0]	
Infiltration Cellular, Plasma Cell	1 [3.0]					
Pigmentation		2 [3.0]		1 [3.0]		
Lymph Node, Mesenteric	(49)	(48)	(47)	(47)	(50)	
Angiectasis	1 [2.0]	2 [3.5]	3 [2.7]			
Atrophy	1 [3.0]	1 [2.0]	1 [2.0]	3 [2.3]		
Ectasia		1 [2.0]		1 [2.0]		
Hematopoietic Cell Proliferation	2 [2.0]	2 [2.0]		2 [2.0]		
Hemorrhage	6 [2.3]	4 [2.5]	6 [2.0]	2 [1.0]	1 [1.0]	
Hyperplasia, Lymphoid	2 [2.0]	5 [2.6]	4 [2.0]	5 [2.0]	3 [2.7]	
Infiltration Cellular, Plasma Cell				1 [2.0]		
Pigmentation		1 [3.0]				

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

(50)

(0)

0 MG/KG 3 MG/KG 6 MG/KG **12 MG/KG** 25 MG/KG **B6C3F1 MICE MALE** Spleen (50)(50)(50)(49)(50)Accessory Spleen 1 Angiectasis 1 [2.0] Hematopoietic Cell Proliferation 20 [2.7] 26 [2.8] 24 [2.8] 25 [2.8] 9 [2.4] Pigmentation 1 [3.0] Lymphoid Follicle, Atrophy 3 [3.0] 2 [2.5] 1 [3.0] 1 [3.0] Lymphoid Follicle, Hyperplasia 1 [1.0] 5 [1.6] 5 [2.0] 3 [1.7] 1 [2.0] **Thymus** (44)(43)(44)(40)(49)Atrophy 3 [2.0] 8 [2.6] 4 [2.5] 6 [2.8] 2 [2.5] Cyst 1 [3.0] 2 [3.0] 1 [3.0] 4 [3.0] Hyperplasia, Lymphoid 1 [3.0] 1 [3.0] 1 [3.0] INTEGUMENTARY SYSTEM Skin (50)(50)(50)(50)(50)Cyst Epithelial Inclusion 2 Edema 1 [2.0] 1 [3.0] 2 [2.5] **Fibrosis** 1 [4.0] Inflammation, Chronic 1 [2.0] 2 [3.5] Ulcer 2 [4.0] Epidermis, Hyperplasia 2 [2.0] 1 [4.0]

NERVOUS SYSTEM

Skeletal Muscle

Hyperostosis

Bone

MUSCULOSKELETAL SYSTEM

Cranium, Osteopetrosis

Brain	(50)	(50)	(50)	(50)	(50)
Necrosis				1 [3.0]	
Pigmentation					1 [1.0]

(50)

1 [2.0]

1 [2.0]

(1)

(50)

(3)

(49)

2 [3.0]

(1)

(50)

1 [3.0]

1 [2.0]

(2)

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
RESPIRATORY SYSTEM						
Lung	(50)	(50)	(50)	(50)	(50)	
Foreign Body			1		1	
Hemorrhage	2 [1.5]	1 [1.0]	1 [1.0]		5 [1.2]	
Infiltration Cellular, Histiocyte		1 [2.0]	1 [2.0]	1 [2.0]		
Inflammation, Chronic Active		1 [1.0]				
Metaplasia, Osseous		1 [1.0]	1 [1.0]		1 [1.0]	
Thrombosis				2 [1.5]		
Alveolar Epithelium, Hyperplasia	3 [1.3]	1 [1.0]	5 [1.4]	4 [2.3]		
Nose	(50)	(50)	(50)	(50)	(50)	
Foreign Body	()	2	1	2	()	
Inflammation, Chronic	5 [1.4]	3 [1.3]	4 [1.3]	3 [1.7]	2 [1.5]	
Respiratory Epithelium, Hyperplasia	1 [2.0]	5 [5]	. []	2 []	_[•]	
SPECIAL SENSES SYSTEM						
Eye	(50)	(50)	(50)	(50)	(50)	
Atrophy	1 [4.0]	()	()	()	()	
Cataract	,	1 [2.0]				
Inflammation, Chronic		3 [2.3]	2 [2.0]		1 [3.0]	
Cornea, Hyperplasia		2 [1.5]	1 [2.0]		11	
Cornea, Ulcer		-[]	. []		1 [3.0]	
Harderian Gland	(50)	(50)	(50)	(50)	(49)	
Atrophy	(00)	(00)	(00)	1 [3.0]	(10)	
Hyperplasia, Focal	1 [2.0]	4 [2.0]		2 [2.0]		
URINARY SYSTEM						
Kidney	(50)	(50)	(50)	(50)	(50)	
Cyst	11 [2.9]	15 [3.0]	9 [3.0]	9 [3.0]	1 [2.0]	
Hydronephrosis	11[2.3]	15 [3.0] 1 [2.0]	၁ [၁.ပ]	၁ [၁.ပ]	1 [2.0] 1 [2.0]	
Infarct	2 [2.5]		6 [1.5]	5 [1.6]	1 [2.0] 1 [3.0]	
inald	د [۷.۵]	3 [2.7]	נכ.ון ט	J [1.0]	ا [٥.٥]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57
First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

Species/Strain: MICE/B6C3F1

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
	4 [0.0]	0.10.01	5 10 41	5 10 01	4 [0.0]	
Infiltration Cellular, Lymphocyte	1 [3.0]	6 [2.8]	5 [2.4]	5 [2.2]	1 [3.0]	
Metaplasia, Osseous	2 [2.0]		5 [2.0]	6 [1.7]	1 [1.0]	
Necrosis			1 [3.0]			
Nephropathy	40 [1.4]	41 [1.7]	38 [1.5]	38 [1.4]	16 [1.4]	
Artery, Inflammation, Chronic Active				1 [3.0]		
Papilla, Necrosis					1 [2.0]	
Renal Tubule, Dilatation, Focal					1 [2.0]	
Renal Tubule, Hyperplasia					1 [2.0]	
Renal Tubule, Pigmentation	1 [2.0]	3 [2.7]		1 [3.0]		
Urethra	(0)	(1)	(0)	(0)	(0)	
Hemorrhage		1 [4.0]				
Inflammation, Acute		1 [3.0]				
Urinary Bladder	(50)	(50)	(50)	(50)	(50)	
Dilatation		1 [4.0]		1 [4.0]		
Infiltration Cellular, Lymphocyte	2 [2.0]					
Transitional Epithelium, Hyperplasia					1 [2.0]	
	,					

*** END OF MALE ***

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Disposition Summary						
Animals Initially In Study	50	50	50	50	50	
Early Deaths						
Accidently Killed	2				1	
Dosing Accident		6			4	
Moribund Sacrifice	4	4	2	3	8	
Natural Death	7	6	8	6	37	
Survivors						
Natural Death			1			
Terminal Sacrifice	37	33	39	41		
Animals Examined Microscopically	50	49	50	50	50	
ALIMENTARY SYSTEM						
Esophagus	(50)	(48)	(49)	(50)	(50)	
Inflammation, Acute	, ,	6 [3.7]			4 [2.8]	
Ulcer		4 [4.0]			2 [2.5]	
Submucosa, Edema			1 [2.0]		1 [2.0]	
Gallbladder	(43)	(39)	(43)	(46)	(46)	
Inflammation, Acute	1 [1.0]	, ,			` '	
Pigmentation				2 [4.0]		
Epithelium, Cytoplasmic Alteration	1 [2.0]					
Intestine Large, Cecum	(48)	(46)	(46)	(49)	(49)	
Edema	, ,	, ,		2 [3.0]	` '	
Intestine Small, Duodenum	(46)	(44)	(45)	(46)	(48)	
Diverticulum				1		
Intestine Small, Ileum	(48)	(47)	(45)	(49)	(48)	
Epithelium, Hyperplasia				1 [3.0]		
Intestine Small, Jejunum	(47)	(47)	(45)	(48)	(47)	
Hyperplasia, Lymphoid	1 [3.0]			1 [3.0]		
Epithelium, Hyperplasia	1 [3.0]					
Liver	(50)	(49)	(49)	(50)	(50)	
Angiectasis	1 [3.0]	·	1 [1.0]	•	·	
Basophilic Focus	1	2	-	4		
Clear Cell Focus	3	2	4	2		

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Cyst	1 [3.0]					
Eosinophilic Focus	3	3	3	4		
Hematopoietic Cell Proliferation	3 [2.7]	3 [2.3]	3 [2.0]	2 [2.5]		
Infiltration Cellular, Lymphocyte	2 [2.5]	1 [3.0]	0 [2.0]	4 [2.0]		
Inflammation, Chronic Active	4 [1.3]	3 [2.3]	2 [2.0]	7 [1.6]		
Mixed Cell Focus	1	5	2 [2.0]	5		
Necrosis, Focal	2 [2.5]	6 [1.7]	3 [1.3]	Ü	2 [1.0]	
Necrosis, Diffuse	2 [2.0]	1 [2.0]	0 [1.0]	1 [1.0]	2[1.0]	
Tension Lipidosis	1	1	2	1		
Centrilobular, Necrosis	·	1 [1.0]	2 [2.5]	•		
Hepatocyte, Hyperplasia, Focal		1 [1.0]	1 [2.0]			
Hepatocyte, Vacuolization Cytoplasmic	7 [2.9]	3 [3.7]	2 [3.5]	2 [3.5]		
Kupffer Cell, Hyperplasia	2 [2.5]	1 [2.0]	1 [3.0]	1 [3.0]		
Mesentery	(10)	(6)	(5)	(6)	(0)	
Necrosis	1 [2.0]	(0)	(0)	(0)	(0)	
Fat, Necrosis	8 [2.6]	6 [3.3]	3 [3.0]	6 [3.2]		
Pancreas	(48)	(49)	(48)	(50)	(50)	
Atrophy	2 [2.5]	1 [1.0]	2 [4.0]	1 [4.0]	1 [1.0]	
Basophilic Focus	1	1	1	. [0]	. [0]	
Cyst	1 [3.0]	·	2 [3.0]	3 [3.0]		
Infiltration Cellular, Lymphocyte	3 [3.0]		1 [2.0]	1 [3.0]		
Acinus, Cytoplasmic Alteration	2 [3.0]		1 [2.0]	. [0.0]		
Salivary Glands	(49)	(48)	(49)	(50)	(50)	
Infiltration Cellular, Lymphocyte	11 [2.6]	13 [2.4]	19 [2.5]	13 [2.4]	(00)	
Stomach, Forestomach	(50)	(49)	(48)	(50)	(50)	
Diverticulum	(00)	1	1	(00)	(00)	
Erosion		·	·	1 [1.0]		
Inflammation, Chronic			1 [2.0]	. [•]		
Epithelium, Hyperplasia			1 [2.0]	2 [3.0]	1 [2.0]	
Stomach, Glandular	(48)	(49)	(47)	(48)	(50)	
Cyst	2 [3.0]	1 [3.0]	2 [3.0]	2 [3.0]	(00)	
Epithelium, Cytoplasmic Alteration	- [0.0]	. [0.0]	- [0.0]	1 [2.0]		
Epithelium, Hyperplasia	1 [2.0]			1 [2.0]		
Tongue	(0)	(0)	(0)	(0)	(1)	
Cyst	(-)	(-)	(-)	(-)	1 [3.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
CARDIOVASCULAR SYSTEM						
Heart Cardiomyopathy Inflammation, Acute	(50)	(49) 1 [3.0] 2 [2.0]	(50)	(50)	(50)	
Mineralization	1 [1.0]	2 [1.0]	1 [2.0]	1 [3.0]		
ENDOCRINE SYSTEM						
Adrenal Cortex	(50)	(49)	(49)	(50)	(50)	
Accessory Adrenal Cortical Nodule Amyloid Deposition	7 [3.0]	5 [3.0]	6 [3.0]	9 [3.0] 1 [3.0]	3 [3.0]	
Degeneration, Fatty	1 [3.0]			1 [3.0]		
Hyperplasia, Focal	2 [2.0]	1 [2.0]	1 [2.0]			
Hypertrophy, Focal			1 [2.0]	2 [3.0]		
Capsule, Hyperplasia	1 [2.0]	5 [1.8]		4 [1.8]		
Subcapsular, Cyst					1 [2.0]	
Subcapsular, Hyperplasia, Focal	4			1 [2.0]	4.5	
Adrenal Medulla	(50)	(47)	(46)	(48)	(49)	
Hyperplasia	1 [1.0]	1 [1.0]		1 [1.0]		
Islets, Pancreatic	(48)	(49)	(48)	(50)	(50)	
Cyst		1 [2.0]				
Hyperplasia	1 [1.0]		2 [3.0]	4 [2.0]		
Parathyroid Gland	(45)	(42)	(46)	(47)	(49)	
Cyst	2 [3.0]		1 [3.0]		4 [3.0]	
Hyperplasia			1 [2.0]			
Pituitary Gland	(49)	(48)	(48)	(49)	(47)	
Pars Distalis, Cyst	3 [3.0]	2 [3.0]		3 [3.0]		
Pars Distalis, Cytoplasmic Alteration, Focal	1 [2.0]					
Pars Distalis, Hemorrhage				1 [3.0]		
Pars Distalis, Hyperplasia, Focal	9 [1.7]	4 [1.5]	7 [1.4]	4 [2.0]		
Rathke's Cleft, Dilatation	-	-	· -		1 [1.0]	
Thyroid Gland	(50)	(48)	(48)	(49)	(49)	
Artery, Inflammation, Chronic Active		1 [3.0]				

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Follicle, Cyst Follicle, Degeneration, Focal Follicular Cell, Hyperplasia	1 [3.0] 28 [2.1]	2 [3.0] 15 [2.3]	28 [2.0]	23 [2.2] 3 [1.0]	2 [1.0]	
GENERAL BODY SYSTEM						
Tissue NOS	(1)	(0)	(0)	(0)	(0)	
GENITAL SYSTEM						
Clitoral Gland	(48)	(46)	(48)	(49)	(47)	
Ovary	(48)	(47)	(49)	(48)	(50)	
Amyloid Deposition				1 [3.0]		
Angiectasis	1 [3.0]	1 [3.0]	2 [4.0]	4 [2.8]		
Cyst	15 [3.0]	14 [3.0]	14 [3.0]	14 [3.0]	2 [3.5]	
Hemorrhage	7 [2.3]	5 [2.0]	13 [2.2]	10 [2.1]		
Inflammation, Granulomatous		1 [3.0]				
Mineralization		1 [3.0]				
Pigmentation			2 [3.0]			
Thrombosis	1 [4.0]		1 [4.0]			
Granulosa Cell, Hyperplasia		1 [3.0]				
Uterus	(50)	(49)	(50)	(50)	(50)	
Amyloid Deposition				1 [2.0]		
Angiectasis	1 [4.0]	1 [2.0]	2 [3.0]	4 [3.5]		
Infiltration Cellular, Histiocyte	1 [3.0]					
Inflammation, Suppurative	1 [3.0]					
Inflammation, Acute		1 [2.0]		1 [2.0]		
Necrosis		- -		1 [3.0]		
Pigmentation	1 [3.0]			- -		
Thrombosis	1 [3.0]	1 [4.0]	1 [4.0]	1 [3.0]		
Endometrium, Hyperplasia, Cystic	39 [2.9]	26 [2.3]	34 [2.0]	35 [2.3]	15 [1.4]	
Myometrium, Hypertrophy		1 [3.0]				

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P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
HEMATOPOIETIC SYSTEM						
Bone Marrow	(50)	(49)	(49)	(50)	(50)	
Angiectasis		1 [3.0]				
Hyperplasia	19 [2.8]	20 [3.0]	13 [2.8]	16 [2.7]	5 [3.0]	
Myelofibrosis		1 [2.0]				
Lymph Node	(6)	(3)	(3)	(1)	(0)	
Bronchial, Atrophy		1 [4.0]				
Bronchial, Pigmentation		1 [3.0]				
Iliac, Ectasia	1 [4.0]					
Iliac, Hematopoietic Cell Proliferation	1 [2.0]					
Mediastinal, Atrophy		1 [4.0]				
Mediastinal, Ectasia	1 [3.0]					
Mediastinal, Pigmentation		1 [3.0]				
Lymph Node, Mandibular	(48)	(46)	(45)	(48)	(49)	
Atrophy	1 [2.0]					
Hematopoietic Cell Proliferation	2 [2.0]		1 [2.0]		1 [1.0]	
Hyperplasia, Lymphoid	9 [2.0]	6 [2.5]	7 [2.3]	2 [2.0]	3 [2.0]	
Infiltration Cellular, Histiocyte				1 [2.0]		
Pigmentation	4 [3.0]	3 [3.0]	4 [3.0]	3 [3.0]		
Lymph Node, Mesenteric	(46)	(49)	(46)	(48)	(47)	
Atrophy		2 [3.0]	1 [2.0]	1 [3.0]	1 [3.0]	
Ectasia	1 [4.0]			2 [4.0]		
Hematopoietic Cell Proliferation			1 [2.0]	1 [3.0]		
Hemorrhage	2 [2.5]	4 [2.8]	1 [3.0]	4 [3.8]		
Hyperplasia, Lymphoid	6 [2.8]	6 [2.2]	2 [2.5]	7 [2.3]		
Infiltration Cellular, Histiocyte				1 [3.0]		
Necrosis		1 [3.0]				
Pigmentation	1 [3.0]			1 [3.0]		
Spleen	(50)	(49)	(48)	(50)	(50)	
Amyloid Deposition	1 [3.0]					
Atrophy				1 [3.0]		
Hematopoietic Cell Proliferation	33 [2.4]	39 [2.6]	36 [2.4]	37 [2.2]	5 [2.4]	
Pigmentation	1 [3.0]			1 [3.0]	1 [2.0]	
Lymphoid Follicle, Atrophy				1 [3.0]		
Lymphoid Follicle, Hyperplasia	12 [2.3]	14 [2.5]	12 [2.4]	17 [2.4]		

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Thymus	(46)	(45)	(46)	(48)	(49)	
Atrophy	4 [2.5]	8 [2.9]	5 [2.6]	6 [3.0]	3 [3.0]	
Cyst		1 [3.0]				
Hemorrhage	1 [3.0]	1 [3.0]				
Hyperplasia, Lymphoid	6 [1.7]	1 [3.0]	2 [1.5]	4 [1.8]	1 [1.0]	
Inflammation, Chronic Active		3 [3.7]			3 [3.0]	
INTEGUMENTARY SYSTEM						
Mammary Gland	(50)	(49)	(50)	(50)	(50)	
Hyperplasia	5 [1.4]	5 [1.8]	3 [2.0]	6 [1.8]		
Skin	(50)	(49)	(50)	(50)	(50)	
Cyst Epithelial Inclusion				1		
Edema		1 [3.0]		1 [2.0]		
Hemorrhage					1 [3.0]	
Inflammation, Chronic Active		1 [2.0]				
Ulcer	2 [2.5]	1 [4.0]				
Subcutaneous Tissue, Inflammation, Chronic Active		1 [3.0]				
MUSCULOSKELETAL SYSTEM						
Bone	(50)	(49)	(50)	(50)	(50)	
Fibrosis	1 [2.0]	2 [2.0]	1 [2.0]	3 [2.3]	, ,	
Fracture	1		2			
Femur, Hyperostosis	1 [3.0]					
Skeletal Muscle	(3)	(2)	(0)	(0)	(0)	
NERVOUS SYSTEM						
Brain	(50)	(49)	(50)	(50)	(50)	
Compression	1 [4.0]	(10)	(00)	1 [4.0]	(00)	
Cyst Epithelial Inclusion	1			. []		
Hemorrhage	-			1 [3.0]	1 [1.0]	
				. []	. []	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

Cataract

Inflammation, Chronic

Cornea, Hyperplasia

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57 First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Necrosis	1 [2.0]			1 [2.0]		
Artery, Meninges, Inflammation, Chronic Active		1 [2.0]				
RESPIRATORY SYSTEM						
Lung	(50)	(49)	(50)	(50)	(50)	
Fibrosis	. ,	1 [3.0]		, ,	, ,	
Foreign Body		8			5	
Hemorrhage	2 [2.5]		1 [2.0]	7 [1.9]	6 [1.7]	
Infiltration Cellular, Histiocyte			1 [2.0]			
Infiltration Cellular, Lymphocyte	2 [2.5]		2 [2.0]	4 [2.3]		
Inflammation, Suppurative		1 [4.0]				
Inflammation, Granulomatous		1 [3.0]				
Inflammation, Acute		4 [3.5]	1 [3.0]			
Inflammation, Chronic	1 [2.0]				1 [2.0]	
Inflammation, Chronic Active		2 [3.5]			1 [1.0]	
Metaplasia, Osseous			1 [2.0]			
Thrombosis	1 [1.0]			1 [2.0]		
Alveolar Epithelium, Hyperplasia	1 [1.0]	1 [1.0]	1 [3.0]			
Arteriole, Hypertrophy					1 [2.0]	
Nose	(50)	(49)	(50)	(50)	(50)	
Foreign Body	1	4				
Inflammation, Chronic	2 [1.0]	4 [1.0]	2 [1.0]			
Pleura	(0)	(0)	(0)	(0)	(4)	
Inflammation, Acute					4 [4.0]	
Trachea	(50)	(49)	(50)	(50)	(50)	
Inflammation, Chronic Active					1 [4.0]	
SPECIAL SENSES SYSTEM						
Eye	(50)	(49)	(50)	(50)	(50)	
Atrophy	(55)	1 [4.0]	(30)	1 [4.0]	(55)	
, opinj		. [1.0]	0.10.01	. []		

1 [1.0]

2 [2.0]

1 [2.0]

2 [3.0]

2 [2.0]

2 [1.0]

2 [2.0]

1 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 08/11/2010 AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture CAS Number: THUJONEMIXAB

Time Report Requested: 13:12:57

First Dose M/F: 06/30/03 / 06/30/03

Lab: SRI

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	6 MG/KG	12 MG/KG	25 MG/KG	
Harderian Gland	(50)	(49)	(50)	(49)	(50)	
Cyst		, ,	1 [3.0]	, ,	, ,	
Hyperplasia, Focal	1 [1.0]	1 [3.0]	1 [1.0]	1 [1.0]		
Infiltration Cellular, Lymphocyte			1 [3.0]			
URINARY SYSTEM						
Kidney	(50)	(49)	(49)	(50)	(50)	
Amyloid Deposition				1 [4.0]		
Cyst	3 [3.0]	3 [3.0]		1 [3.0]		
Glomerulosclerosis		1 [3.0]				
Infarct	2 [2.5]	5 [2.4]	6 [1.8]	1 [1.0]		
Infiltration Cellular, Lymphocyte	3 [2.3]	9 [2.6]	5 [2.2]	5 [2.8]		
Inflammation, Chronic	1 [3.0]					
Metaplasia, Osseous	1 [3.0]	1 [2.0]	2 [1.5]	3 [2.3]		
Mineralization				1 [2.0]		
Nephropathy	11 [1.5]	11 [1.3]	5 [1.0]	7 [1.7]	3 [1.0]	
Renal Tubule, Accumulation, Hyaline Droplet	1 [3.0]	2 [3.0]	1 [3.0]	2 [2.5]	-	
Renal Tubule, Cytoplasmic Alteration			1 [3.0]			
Renal Tubule, Pigmentation	1 [3.0]		2 [3.0]			
Urinary Bladder	(50)	(49)	(49)	(50)	(50)	
Infiltration Cellular, Lymphocyte	2 [2.0]	1 [2.0]	2 [3.0]	4 [2.8]	` '	

*** END OF REPORT ***

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