Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

Route: SKIN APPLICATION

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

Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

CAS Number: 120-40-1

Time Report Requested: 09:56:09

First Dose M/F: NA / NA

Lab: ILS

C Number: C55232C

Lock Date: 08/21/1997

Cage Range: ΑII

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Both

PWG Approval Date NONE

Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 09:56:09

Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

CAS Number: 120-40-1

Time Report Requested: 09:56:09

First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	5.0 MG	10.0 MG	20.0 MG
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice	1	1		
Survivors				
Terminal Sacrifice	9	9	10	10
Animals Examined Microscopically	10			10
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(10)
Centrilobular, Vacuolization Cytoplasmic	2 [1.0]			
Infiltration Cellular, Lymphocyte				2 [1.0]
Infiltration Cellular, Mixed Cell	3 [1.0]			2 [1.0]
Infiltration Cellular, Mononuclear Cl	1 [1.0]			
Midzonal, Hypertrophy	7 [1.0]			6 [1.0]
Necrosis				1 [1.0]
Salivary Glands	(10)	(0)	(0)	(10)
Artery, Submandibul GI, Inflammation	1 [3.0]			
Parotid GI, Basophilic Focus				1 [1.0]
Submandibul GI, Infiltration Cellular, Lymphocyte	8 [1.3]			8 [1.1]
Stomach, Forestomach	(10)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(10)
Artery, Inflammation	1 [2.0]			
Cyst	1 [1.0]			4 [1.0]
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
Adrenal Cortex	(9)	(0)	(0)	(8)

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)

Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

NERVOUS SYSTEM

None

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/23/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 09:56:10

Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

CAS Number: 120-40-1

Time Report Requested: 09:56:10

First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	5.0 MG	10.0 MG	20.0 MG
Capsule, Hyperplasia				2 [1.0]
Degeneration, Fatty	8 [1.0]			8 [1.3]
Hypertrophy	1 [2.0]			1 [1.0]
Adrenal Medulla	(8)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(9)
Pars Distalis, Cyst	1 [1.0]			
Thyroid Gland	(10)	(0)	(0)	(8)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(10)
Hyperplasia	1 [3.0]			
Spleen	(10)	(0)	(0)	(10)
Hematopoietic Cell Proliferation	4 [2.8]			1 [1.0]
Infiltration Cellular, Lymphocyte				1 [2.0]
Thymus	(9)	(0)	(0)	(10)
Cyst	4 [1.3]			5 [1.2]
INTEGUMENTARY SYSTEM				
Skin	(10)	(0)	(0)	(10)
Hyperplasia, Squamous	, ,	· · ·	` '	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: 26-WEEK

Route: SKIN APPLICATION

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Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

Species/Strain: Mouse/P53(C57BL/6)

CAS Number: 120-40-1

Time Report Requested: 09:56:10

First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	5.0 MG	10.0 MG	20.0 MG
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(10)
Hyperplasia				1 [1.0]
Infiltration Cellular, Lymphocyte	2 [1.0]			6 [1.3]
SPECIAL SENSES SYSTEM None URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(10)
Artery, Inflammation	1 [2.0]	(0)	(0)	(10)
Congestion	2 [1.0]			
Infiltration Cellular, Lymphocyte	1 [1.0]			3 [1.0]
Nephropathy	4 [1.0]			5 [1.0]
Pelvis, Dilatation				1 [1.0]

^{***}END OF MALE DATA***

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)

Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 09:56:10

Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

CAS Number: 120-40-1

Time Report Requested: 09:56:10

First Dose M/F: NA / NA

P53(C57BL/6) Mouse FEMALE	0 MG	5.0 MG	10.0 MG	20.0 MG
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice	1			
Survivors				
Terminal Sacrifice	9	10	10	9
Other				1
Animals Examined Microscopically	10			10
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(10)
Infiltration Cellular, Lymphocyte	2 [2.0]			3 [2.0]
Infiltration Cellular, Mixed Cell	3 [1.0]			1 [1.0]
Infiltration Cellular, Mononuclear Cl	3 [1.0]			4 [1.3]
Midzonal, Hypertrophy	1 [1.0]			1 [1.0]
Necrosis	1 [3.0]			
Salivary Glands	(10)	(0)	(0)	(10)
Submandibul GI, Infiltration Cellular, Lymphocyte	3 [2.3]			5 [1.4]
Submandibul GI, Infiltration Cellular, Plasma Cell	2 [1.0]			
Stomach, Forestomach	(10)	(0)	(0)	(10)
Hyperplasia	1 [1.0]			
Stomach, Glandular	(10)	(0)	(0)	(10)
Cyst	3 [1.0]			3 [1.3]
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
Adrenal Cortex	(10)	(0)	(0)	(9)

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: 26-WEEK

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 09:56:10

Test Compound: Transgenic LECM (Lauric acid diethanolamine condensate)

Species/Strain: Mouse/P53(C57BL/6)

CAS Number: 120-40-1

Time Report Requested: 09:56:10

First Dose M/F: NA / NA

Lab: ILS

P53(C57BL/6) Mouse FEMALE	0 MG	5.0 MG	10.0 MG	20.0 MG
Capsule, Hyperplasia	9 [1.0]			8 [1.4]
Degeneration, Fatty	7 [1.0]			1 [1.0]
Adrenal Medulla	(10)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(10)
Pars Distalis, Cyst	1 [1.0]			1 [1.0]
Thyroid Gland	(9)	(0)	(0)	(10)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Uterus	(1)	(0)	(0)	(0)
Hyperplasia, Cystic	1 [3.0]			
HEMATOPOIETIC SYSTEM				
Lymph Node	(0)	(0)	(0)	(1)
Lymph Node, Mandibular	(10)	(0)	(0)	(9)
Hyperplasia	3 [2.0]			
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	6 [2.3]			2 [3.0]
Thymus	(9)	(0)	(0)	(10)
Cyst	3 [1.3]			6 [1.2]
INTEGUMENTARY SYSTEM				
Mammary Gland	(10)	(0)	(0)	(4)
Skin	(10)	(0)	(0)	(10)
Hyperkeratosis				1 [4.0]
Hyperplasia, Squamous				2 [2.5]
Ulcer				1 [2.0]

MUSCULOSKELETAL SYSTEM

None

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Species/Strain: Mouse/P53(C57BL/6)

Test Type: 26-WEEK

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CAS Number: 120-40-1

Time Report Requested: 09:56:10

First Dose M/F: NA / NA

P53(C57BL/6) Mouse FEMALE	0 MG	5.0 MG	10.0 MG	20.0 MG
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(10)
Infiltration Cellular, Histiocyte	1 [1.0]			
Infiltration Cellular, Lymphocyte	3 [1.3]			1 [1.0]
Infiltration Cellular, Mononuclear Cl	1 [1.0]			
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(10)
Casts Protein	2 [1.0]			
Infiltration Cellular, Lymphocyte	3 [1.3]			3 [1.0]
Infiltration Cellular, Mononuclear Cl				1 [1.0]
Nephropathy				1 [1.0]

^{**} END OF REPORT **

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)