

**Experiment Number:** 55323-05  
**Test Type:** 26-WEEK  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/P53(C57BL/6)

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

**Test Compound:** Transgenic LECM (Lauric acid diethanolamine condensate)

**CAS Number:** 120-40-1

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 09:56:30

**First Dose M/F:** NA / NA

**Lab:** ILS

<b>C Number:</b>	C55232C
<b>Lock Date:</b>	08/21/1997
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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P53(C57BL/6) Mouse MALE	0 MG	5.0 MG	10.0 MG	20.0 MG
<b>Disposition Summary</b>				
<b>Animals Initially In Study</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>1</b>	<b>1</b>		
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>9</b>	<b>9</b>	<b>10</b>	<b>10</b>
<b>Animals Examined Microscopically</b>	<b>10</b>			<b>10</b>
<b>ALIMENTARY SYSTEM</b>				
Liver	(10)	(0)	(0)	(10)
Centrilobular, Vacuolization Cytoplasmic	2 (20%)			
Infiltration Cellular, Lymphocyte				2 (20%)
Infiltration Cellular, Mixed Cell	3 (30%)			2 (20%)
Infiltration Cellular, Mononuclear Cl	1 (10%)			
Midzonal, Hypertrophy	7 (70%)			6 (60%)
Necrosis				1 (10%)
Salivary Glands	(10)	(0)	(0)	(10)
Artery, Submandibul GI, Inflammation	1 (10%)			
Parotid GI, Basophilic Focus				1 (10%)
Submandibul GI, Infiltration Cellular, Lymphocyte	8 (80%)			8 (80%)
Stomach, Forestomach	(10)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(10)
Artery, Inflammation	1 (10%)			
Cyst	1 (10%)			4 (40%)
<b>CARDIOVASCULAR SYSTEM</b>				
None				
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(9)	(0)	(0)	(8)
Capsule, Hyperplasia				2 (25%)

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

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P53(C57BL/6) Mouse MALE	0 MG	5.0 MG	10.0 MG	20.0 MG
Degeneration, Fatty	8 (89%)			8 (100%)
Hypertrophy	1 (11%)			1 (13%)
Adrenal Medulla	(8)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(9)
Pars Distalis, Cyst	1 (11%)			
Thyroid Gland	(10)	(0)	(0)	(8)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(10)
Hyperplasia	1 (10%)			
Spleen	(10)	(0)	(0)	(10)
Hematopoietic Cell Proliferation	4 (40%)			1 (10%)
Infiltration Cellular, Lymphocyte				1 (10%)
Thymus	(9)	(0)	(0)	(10)
Cyst	4 (44%)			5 (50%)
INTEGUMENTARY SYSTEM				
Skin	(10)	(0)	(0)	(10)
Hyperplasia, Squamous				1 (10%)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(10)

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<b>P53(C57BL/6) Mouse MALE</b>	<b>0 MG</b>	<b>5.0 MG</b>	<b>10.0 MG</b>	<b>20.0 MG</b>
Hyperplasia				1 (10%)
Infiltration Cellular, Lymphocyte	2 (20%)			6 (60%)
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(10)
Artery, Inflammation	1 (10%)			
Congestion	2 (20%)			
Infiltration Cellular, Lymphocyte	1 (10%)			3 (30%)
Nephropathy	4 (40%)			5 (50%)
Pelvis, Dilatation				1 (10%)

\*\*\*END OF MALE DATA\*\*\*

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P53(C57BL/6) Mouse FEMALE	0 MG	5.0 MG	10.0 MG	20.0 MG
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
Liver	(10)	(0)	(0)	(10)
Infiltration Cellular, Lymphocyte	2 (20%)			3 (30%)
Infiltration Cellular, Mixed Cell	3 (30%)			1 (10%)
Infiltration Cellular, Mononuclear Cl	3 (30%)			4 (40%)
Midzonal, Hypertrophy	1 (10%)			1 (10%)
Necrosis	1 (10%)			
Salivary Glands	(10)	(0)	(0)	(10)
Submandibul GI, Infiltration Cellular, Lymphocyte	3 (30%)			5 (50%)
Submandibul GI, Infiltration Cellular, Plasma Cell	2 (20%)			
Stomach, Forestomach	(10)	(0)	(0)	(10)
Hyperplasia	1 (10%)			
Stomach, Glandular	(10)	(0)	(0)	(10)
Cyst	3 (30%)			3 (30%)
<b>CARDIOVASCULAR SYSTEM</b>				
None				
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(10)	(0)	(0)	(9)
Capsule, Hyperplasia	9 (90%)			8 (89%)

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

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<b>P53(C57BL/6) Mouse FEMALE</b>	<b>0 MG</b>	<b>5.0 MG</b>	<b>10.0 MG</b>	<b>20.0 MG</b>
Degeneration, Fatty	7 (70%)			1 (11%)
Adrenal Medulla	(10)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(10)
Pars Distalis, Cyst	1 (11%)			1 (10%)
Thyroid Gland	(9)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Uterus	(1)	(0)	(0)	(0)
Hyperplasia, Cystic	1 (100%)			
<b>HEMATOPOIETIC SYSTEM</b>				
Lymph Node	(0)	(0)	(0)	(1)
Lymph Node, Mandibular	(10)	(0)	(0)	(9)
Hyperplasia	3 (30%)			
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	6 (60%)			2 (22%)
Thymus	(9)	(0)	(0)	(10)
Cyst	3 (33%)			6 (60%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(10)	(0)	(0)	(4)
Skin	(10)	(0)	(0)	(10)
Hyperkeratosis				1 (10%)
Hyperplasia, Squamous				2 (20%)
Ulcer				1 (10%)
<b>MUSCULOSKELETAL SYSTEM</b>				
None				
<b>NERVOUS SYSTEM</b>				

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

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<b>P53(C57BL/6) Mouse FEMALE</b>	<b>0 MG</b>	<b>5.0 MG</b>	<b>10.0 MG</b>	<b>20.0 MG</b>
None				
<b>RESPIRATORY SYSTEM</b>				
Lung	(10)	(0)	(0)	(10)
Infiltration Cellular, Histiocyte	1 (10%)			
Infiltration Cellular, Lymphocyte	3 (30%)			1 (10%)
Infiltration Cellular, Mononuclear CI	1 (10%)			
<b>SPECIAL SENSES SYSTEM</b>				
None				
<b>URINARY SYSTEM</b>				
Kidney	(10)	(0)	(0)	(10)
Casts Protein	2 (20%)			
Infiltration Cellular, Lymphocyte	3 (30%)			3 (30%)
Infiltration Cellular, Mononuclear CI				1 (10%)
Nephropathy				1 (10%)

**\*\* END OF REPORT \*\***