Test Type: 26-WEEK

C Number:

**Route: SKIN APPLICATION** 

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

CAS Number: 68603-42-9

Test Compound: TRANSGENIC LECM (COCONUT OIL DIETHANOLAMINE)

Date Report Requested: 10/23/2014 Time Report Requested: 12:03:19

First Dose M/F: NA / NA

Lab: ILS

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

C55312

**Lock Date:** 08/21/1997

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range:

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

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

Test Type: 26-WEEK

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**CAS Number:** 68603-42-9

Date Report Requested: 10/23/2014 Time Report Requested: 12:03:19

First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Disposition Summary				
Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice	1	1		1
Survivors				
Terminal Sacrifice	9	9	10	9
Animals Examined Microscopically	10			9
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(9)
Centrilobular, Vacuolization Cytoplasmic	1 (10%)			
Infiltration Cellular, Mixed Cell	3 (30%)			
Infiltration Cellular, Mononuclear Cl	1 (10%)			3 (33%)
Midzonal, Hypertrophy	7 (70%)			9 (100%)
Vacuolization Cytoplasmic	1 (10%)			
Salivary Glands	(10)	(0)	(0)	(9)
Artery, Submandibul GI, Inflammation	1 (10%)			
Submandibul GI, Infiltration Cellular, Lymphocyte	8 (80%)			8 (89%)
Stomach, Forestomach	(10)	(0)	(0)	(9)
Stomach, Glandular	(10)	(0)	(0)	(9)
Artery, Inflammation	1 (10%)			
Cyst	1 (10%)			2 (22%)
Inflammation, Suppurative				1 (11%)
Mineralization				1 (11%)
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
Adrenal Cortex	(9)	(0)	(0)	(7)
Accessory Adrenal Cortical Nodule				1 (14%)

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

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

Test Type: 26-WEEK

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First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Capsule, Hyperplasia				3 (43%)
Degeneration, Fatty	8 (89%)			7 (100%)
Hypertrophy	1 (11%)			1 (14%)
Adrenal Medulla	(8)	(0)	(0)	(7)
Pituitary Gland	(9)	(0)	(0)	(8)
Pars Distalis, Cyst	1 (11%)			1 (13%)
Thyroid Gland	(10)	(0)	(0)	(9)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None	,			
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(8)
Hyperplasia	1 (10%)			
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	4 (40%)			3 (33%)
Thymus	(9)	(0)	(0)	(9)
Cyst	4 (44%)			4 (44%)
INTEGUMENTARY SYSTEM				
Skin	(10)	(0)	(0)	(9)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(9)
Congestion	` ,	. ,	. ,	1 (11%)

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

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

Test Type: 26-WEEK

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**CAS Number:** 68603-42-9

Date Report Requested: 10/23/2014 Time Report Requested: 12:03:19

First Dose M/F: NA / NA

P53(C57BL/6) Mouse MALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Infiltration Cellular, Lymphocyte	2 (20%)			2 (22%)
SPECIAL SENSES SYSTEM None				
URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(9)
Artery, Inflammation	1 (10%)			
Congestion	2 (20%)			
Infiltration Cellular, Lymphocyte	1 (10%)			2 (22%)
Infiltration Cellular, Mononuclear Cl				1 (11%)
Nephropathy	4 (40%)			3 (33%)

<sup>\*\*\*</sup>END OF MALE DATA\*\*\*

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

Test Type: 26-WEEK

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**CAS Number:** 68603-42-9

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First Dose M/F: NA / NA

Disposition Summary  Animals Initially In Study	10	10	10	
Animals Initially In Study		10	10	
,			. •	10
Early Deaths				
Moribund Sacrifice	1			
Survivors				
Terminal Sacrifice	9	10	10	9
Missing				1
Animals Examined Microscopically	10			9
ALIMENTARY SYSTEM				
Liver	(10)	(0)	(0)	(9)
Infiltration Cellular, Lymphocyte	2 (20%)			
Infiltration Cellular, Mixed Cell	3 (30%)			4 (44%)
Infiltration Cellular, Mononuclear Cl	3 (30%)			1 (11%)
Midzonal, Hypertrophy	1 (10%)			
Necrosis	1 (10%)			
Salivary Glands	(10)	(0)	(0)	(9)
Submandibul GI, Infiltration Cellular, Lymphocyte	3 (30%)			5 (56%)
Submandibul GI, Infiltration Cellular, Plasma Cell	2 (20%)			
Stomach, Forestomach	(10)	(0)	(0)	(9)
Hyperplasia	1 (10%)			
Stomach, Glandular	(10)	(0)	(0)	(9)
Cyst	3 (30%)			3 (33%)
Inflammation, Suppurative				1 (11%)
CARDIOVASCULAR SYSTEM None				
ENDOCRINE SYSTEM				
Adrenal Cortex	(10)	(0)	(0)	(8)

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

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

Test Type: 26-WEEK

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**CAS Number:** 68603-42-9

Date Report Requested: 10/23/2014 Time Report Requested: 12:03:19

First Dose M/F: NA / NA

P53(C57BL/6) Mouse FEMALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Capsule, Hyperplasia	9 (90%)			7 (88%)
Degeneration, Fatty	7 (70%)			4 (50%)
Adrenal Medulla	(10)	(0)	(0)	(8)
Pituitary Gland	(9)	(0)	(0)	(6)
Pars Distalis, Cyst	1 (11%)			
Thyroid Gland	(9)	(0)	(0)	(9)
GENERAL BODY SYSTEM				
None			,	
GENITAL SYSTEM				
Uterus	(1)	(0)	(0)	(0)
Hyperplasia, Cystic	1 (100%)		,	
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(8)
Hyperplasia	3 (30%)			2 (25%)
Spleen	(10)	(0)	(0)	(9)
Hematopoietic Cell Proliferation	6 (60%)			5 (56%)
Thymus	(9)	(0)	(0)	(9)
Cyst	3 (33%)			5 (56%)
NTEGUMENTARY SYSTEM				
Mammary Gland	(10)	(0)	(0)	(4)
Skin	(10)	(0)	(0)	(9)
MUSCULOSKELETAL SYSTEM				
None			,	
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(9)

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

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

Test Type: 26-WEEK

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First Dose M/F: NA / NA

P53(C57BL/6) Mouse FEMALE	0 MG	2.5 MG	5.0 MG	7.5 MG
Infiltration Cellular, Histiocyte	1 (10%)			6 (67%)
Infiltration Cellular, Lymphocyte	3 (30%)			3 (33%)
Infiltration Cellular, Mononuclear Cl	1 (10%)			
None				
URINARY SYSTEM				
Kidney	(10)	(0)	(0)	(9)
Casts Protein	2 (20%)			
Glomerulus, Inflammation				1 (11%)
Infiltration Cellular, Lymphocyte	3 (30%)			1 (11%)

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