TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR		P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) All-trans-retinyl palmitate CAS Number: 79-81-2	Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR
C Number:	C20117		
Lock Date:	12/01/2008		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	ALL		
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Male		
TDMSE Version:	2.1.0		

TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR

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

All-trans-retinyl palmitate

**CAS Number:** 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLI
Disposition Summary						
Animals Initially in Study Early Deaths	34	36	36	36	36	36
Moribund Sacrifice Natural Death Survivors	5 1	3 2	7 2	2	8 1	7 1
Moribund Sacrifice Terminal Sacrifice	1 27	29	3	1 20	25	1
Harvest Animals Examined Microscopically	34	2 36	24	13	2 35	27 36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						
INTEGUMENTARY SYSTEM						

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

TDMS No. 20117 - 01

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

Test Type: 1-YEAR

**Route: SKIN APPLICATION** 

Species/Strain: MICE/SKH-1/NCTR

All-trans-retinyl palmitate

**CAS Number:** 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
Skin, Control	(34)	(36)	(0)	(0)	(35)	(36)
Abscess	- /	4 (11%)			2 (6%)	1 (3%)
Cyst Epithelial Inclusion	2 (6%)	2 (6%)			6 (17%)	6 (17%)
Hyperplasia, Squamous	1 (3%)					1 (3%)
Infiltration Cellular, Lymphocyte					1 (00())	
Inflammation, Suppurative					1 (3%)	
Necrosis					1 (3%)	
Ulcer Dermis, Inflammation, Suppurative		1 (3%)				
Dermis, Inflammation, Supportative		1 (3%)				2 (6%)
Epidermis, Inflammation, Suppurative	1 (3%)	1 (3%)				2 (0%) 1 (3%)
Epidermis, Necrosis	1 (378)					1 (3%)
Epidermis, Ulcer		1 (3%)				1 (370)
Skin, Site Of Application	(34)	(36)	(0)	(0)	(35)	(36)
Abscess	(04)	(66)	(0)	(0)	(00)	1 (3%)
Cyst Epithelial Inclusion	3 (9%)	5 (14%)			4 (11%)	6 (17%)
Hyperplasia, Squamous Atypical, One, Focal		4 (11%)			5 (14%)	2 (6%)
Hyperplasia, Squamous Atypical, Two, Focal					1 (3%)	2 (6%)
Hyperplasia, Squamous Atypical, Three, Focal					()	5 (14%)
Hyperplasia, Squamous Atypical, Four, Focal					1 (3%)	3 (8%)
Hyperplasia, Squamous Atypical, Five, Focal					2 (6%)	2 (6%)
Hyperplasia, Squamous Atypical, Greater						14 (39%)
Than Five, Focal						
Hyperplasia, Squamous		6 (17%)			4 (11%)	23 (64%)
Keratin Cyst						
Dermis, Inflammation, Chronic Active		3 (8%)			3 (9%)	9 (25%)
Epidermis, Inflammation, Suppurative					1 (3%)	
Epidermis, Necrosis					1 (3%)	3 (8%)
Epidermis, Ulcer		1 (3%)			1 (3%)	
Sebaceous Gland, Hyperplasia						

#### MUSCULOSKELETAL SYSTEM

None

## NERVOUS SYSTEM

None

#### **RESPIRATORY SYSTEM**

20117 - 01 P03: INCIDENCE RATES OF NON-NEOPLASTIC LESION 1-YEAR All-trans-retinyl palmitate A APPLICATION CAS Number: 79-81-2 rain: MICE/SKH-1/NCTR				Date Report Requested: 06/29/2003 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR	
NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
	NO CREAMNO	All-trans-r CAS Nur NO CREAMNO PH 7.0 NO SSL-M	All-trans-retinyl palmitate CAS Number: 79-81-2 NO CREAMNO PH 7.0 NO SSL-M 2% RP NO SSL-M	CAS Number: 79-81-2 NO CREAMNO PH 7.0 NO SSL-M 2% RP NO SSL-M .001% RANO	All-trans-retinyl palmitate Time Report Re CAS Number: 79-81-2 First Dose M/F Lab: NCTR

TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	P03: INCIDENCE	E RATES OF NON-NEO All-trans-ro CAS Nur	Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR			
SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
Disposition Summary						
Animals Initially in Study	36	35	36	36	36	36
Early Deaths Moribund Sacrifice Natural Death Survivors Moribund Sacrifice	3	3	1	4 2	1	1
Terminal Sacrifice Harvest Animals Examined Microscopically	33 36	32 35	35	30	35	35 36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						
INTEGUMENTARY SYSTEM						

a - Number of animals examined microscopically at site and number of animals with lesion Page 5

TDMS No. 20117 - 01

# Test Type: 1-YEAR

**Route: SKIN APPLICATION** 

Species/Strain: MICE/SKH-1/NCTR

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

All-trans-retinyl palmitate

CAS Number: 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
Skin, Control	(36)	(35)	(0)	(0)	(0)	(36)
Abscess	4 (11%)					2 (6%)
Cyst Epithelial Inclusion	1 (3%)	1 (3%)				3 (8%)
Hyperplasia, Squamous						3 (8%)
Infiltration Cellular, Lymphocyte						
Inflammation, Suppurative						1 (3%)
Necrosis						
Ulcer						
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active	1 (3%)					4 (11%)
Epidermis, Inflammation, Suppurative	1 (3%)					1 (3%)
Epidermis, Necrosis						
Epidermis, Ulcer	1 (3%)	()	(-)	(-)	(-)	1 (3%)
Skin, Site Of Application	(36)	(35)	(0)	(0)	(0)	(36)
Abscess						a (aa()
Cyst Epithelial Inclusion	0 (00()	4 (00()				3 (8%)
Hyperplasia, Squamous Atypical, One, Focal	3 (8%)	1 (3%)				3 (8%)
Hyperplasia, Squamous Atypical, Two, Focal	2 (6%)	0 (00()				6 (17%)
Hyperplasia, Squamous Atypical, Three, Focal	0 (00()	2 (6%)				5 (14%)
Hyperplasia, Squamous Atypical, Four, Focal	2 (6%)	2 (6%)				5 (14%)
Hyperplasia, Squamous Atypical, Five, Focal	5 (14%)	3 (9%)				3 (8%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	21 (58%)	23 (66%)				10 (28%)
Hyperplasia, Squamous	32 (89%)	34 (97%)				26 (72%)
Keratin Cyst		- •				
Dermis, Inflammation, Chronic Active	12 (33%)	30 (86%)				5 (14%)
Epidermis, Inflammation, Suppurative	7 (19%)	8 (23%)				1 (3%)
Epidermis, Necrosis	9 (25%)	14 (40%)				3 (8%)
Epidermis, Ulcer	7 (19%)	8 (23%)				1 (3%)
Sebaceous Gland, Hyperplasia						

# MUSCULOSKELETAL SYSTEM

None

## NERVOUS SYSTEM

None

#### RESPIRATORY SYSTEM

TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	P03: INCIDENCE	E RATES OF NON-NEC All-trans-r CAS Nur	Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR			
SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
SPECIAL SENSES SYSTEM						
None URINARY SYSTEM						
None						

TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	P03: INCIDENCE	E RATES OF NON-NEO All-trans-ro CAS Nur	Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR			
SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
Disposition Summary						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths Moribund Sacrifice Natural Death Survivors	3	1	1	2 1	1 1	
Moribund Sacrifice Terminal Sacrifice	22	25	95	22		22
Harvest Animals Examined Microscopically	33 36	35 36	35 36	33	34	36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						
INTEGUMENTARY SYSTEM						

a - Number of animals examined microscopically at site and number of animals with lesion Page 8

TDMS No. 20117 - 01

# P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) All-trans-retinyl palmitate

**CAS Number:** 79-81-2

Test Type: 1-YEAR

Route: SKIN APPLICATION

Species/Strain: MICE/SKH-1/NCTR

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Abscess	2 (6%)	2 (6%)				
Cyst Epithelial Inclusion	2 (6%)	2 (6%)	2 (6%)			
Hyperplasia, Squamous		1 (3%)	2 (6%)			
Infiltration Cellular, Lymphocyte		4 (00()	4 (00()			
Inflammation, Suppurative		1 (3%)	1 (3%)			
Necrosis Ulcer		4 (20()				
Dicer Dermis, Inflammation, Suppurative		1 (3%)				
Dermis, Inflammation, Suppurative	2 (6%)	2 (99/)	2 (6%)			
Epidermis, Inflammation, Suppurative	2 (6%)	3 (8%)	2 (0%)			
Epidermis, Innanimation, Suppurative	2 (078)					
Epidermis, Necrosis	2 (6%)	2 (6%)	1 (3%)			
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Abscess	(88)	(88)	2 (6%)	(0)	(0)	(0)
Cyst Epithelial Inclusion	3 (8%)	1 (3%)	1 (3%)			
Hyperplasia, Squamous Atypical, One, Focal	- ()	1 (3%)	((,,,))			
Hyperplasia, Squamous Atypical, Two, Focal		2 (6%)	2 (6%)			
Hyperplasia, Squamous Atypical, Three, Focal	7 (19%)	4 (11%)	2 (6%)			
Hyperplasia, Squamous Atypical, Four, Focal	× ,	3 (8%)	3 (8%)			
Hyperplasia, Squamous Atypical, Five, Focal	2 (6%)	2 (6%)	2 (6%)			
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	24 (67%)	24 (67%)	26 (72%)			
Hyperplasia, Squamous	27 (75%)	34 (94%)	35 (97%)			
Keratin Cyst	1 (3%)	( ),	× ,			
Dermis, Inflammation, Chronic Active	8 (22%)	20 (56%)	32 (89%)			
Epidermis, Inflammation, Suppurative	3 (8%)	7 (19%)	14 (39%)			
Epidermis, Necrosis	5 (14%)	11 (31%)	20 (56%)			
Epidermis, Ulcer	3 (8%)	8 (22%)	10 (28%)			
Sebaceous Gland, Hyperplasia	1 (3%)	1 (3%)				

#### MUSCULOSKELETAL SYSTEM

None

## NERVOUS SYSTEM

None

#### RESPIRATORY SYSTEM

TDMS No. 20117 - 01 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	P03: INCIDENCE	E RATES OF NON-NEC All-trans-r CAS Nur	Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR			
SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
SPECIAL SENSES SYSTEM						
None URINARY SYSTEM						
None						

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

All-trans-retinyl palmitate **CAS Number:** 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAMM20.55SSL	1% RP NO SSL-M
Disposition Summary		
Animals Initially in Study	36	36
Early Deaths Moribund Sacrifice	1	7
Natural Death Survivors Maritural Securities	1	1
Moribund Sacrifice Terminal Sacrifice	24	8 20
Harvest Animals Examined Microscopically	34 36	20
ALIMENTARY SYSTEM		
None		
CARDIOVASCULAR SYSTEM		
None		
ENDOCRINE SYSTEM		
None		
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
None		
HEMATOPOIETIC SYSTEM		
None		
INTEGUMENTARY SYSTEM		

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

TDMS No. 20117 - 01 Test Type: 1-YEAR

**Route: SKIN APPLICATION** 

Species/Strain: MICE/SKH-1/NCTR

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

All-trans-retinyl palmitate

**CAS Number:** 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAMM20.55SSL	1% RP NO SSL-M		
Skin, Control	(36)	(0)		
Abscess	1 (3%)			
Cyst Epithelial Inclusion	2 (6%)			
Hyperplasia, Squamous	2 (6%)			
Infiltration Cellular, Lymphocyte	1 (3%)			
Inflammation, Suppurative				
Necrosis				
Ulcer				
Dermis, Inflammation, Suppurative				
Dermis, Inflammation, Chronic Active	4 (11%)			
Epidermis, Inflammation, Suppurative	2 (6%)			
Epidermis, Necrosis	1 (3%)			
Epidermis, Ulcer	3 (8%)			
Skin, Site Of Application	(36)	(0)		
Abscess				
Cyst Epithelial Inclusion				
Hyperplasia, Squamous Atypical, One, Focal	2 (6%)			
Hyperplasia, Squamous Atypical, Two, Focal	3 (8%)			
Hyperplasia, Squamous Atypical, Three, Focal	8 (22%)			
Hyperplasia, Squamous Atypical, Four, Focal	4 (11%)			
Hyperplasia, Squamous Atypical, Five, Focal	4 (11%)			
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	9 (25%)			
Hyperplasia, Squamous	18 (50%)			
Keratin Cyst	· · ·			
Dermis, Inflammation, Chronic Active	8 (22%)			
Epidermis, Inflammation, Suppurative	1 (3%)			
Epidermis, Necrosis	2 (6%)			
Epidermis, Ulcer	1 (3%)			
Sebaceous Gland, Hyperplasia	1 (3%)			

## MUSCULOSKELETAL SYSTEM

None

## NERVOUS SYSTEM

None

#### RESPIRATORY SYSTEM

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

All-trans-retinyl palmitate **CAS Number:** 79-81-2

Date Report Requested: 06/29/2009 Time Report Requested: 16:29:37 First Dose M/F: 06/22/03 / NA Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE

NOCREAMM20.55SSL 1% RP NO SSL-M

# SPECIAL SENSES SYSTEM

None

#### URINARY SYSTEM

None

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

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