

**TDMS No.** 20117 - 02

**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:** 16:32:02

**First Dose M/F:** NA / 06/22/03

**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:** Female  
**TDMSE Version:** 2.1.0

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
<b>Disposition Summary</b>						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed						
Moribund Sacrifice		3	16		2	
Natural Death	1		1	1	1	2
Survivors						
Moribund Sacrifice	1	3		1		
Terminal Sacrifice	34	28		29	30	24
Harvest		2	19	5	3	10
Animals Examined Microscopically	36	36			36	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(0)	(0)	(36)	(36)
Abscess	1 (3%)				1 (3%)	
Cyst Epithelial Inclusion	2 (6%)	4 (11%)			4 (11%)	6 (17%)
Edema						
Hyperplasia, Squamous Atypical, Focal						
Hyperplasia, Squamous Ulcer	1 (3%)	1 (3%)				1 (3%)
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active	3 (8%)	1 (3%)			1 (3%)	1 (3%)
Epidermis, Inflammation, Suppurative						
Epidermis, Necrosis						
Epidermis, Ulcer	1 (3%)					
Skin, Site Of Application	(36)	(36)	(0)	(0)	(36)	(36)
Abscess	1 (3%)	1 (3%)				1 (3%)
Cyst, Multiple	1 (3%)					
Cyst Epithelial Inclusion	2 (6%)				4 (11%)	5 (14%)
Hyperplasia, Squamous Atypical, One, Focal					11 (31%)	6 (17%)
Hyperplasia, Squamous Atypical, Two, Focal		1 (3%)			1 (3%)	5 (14%)
Hyperplasia, Squamous Atypical, Three, Focal					2 (6%)	6 (17%)
Hyperplasia, Squamous Atypical, Four, Focal					1 (3%)	3 (8%)
Hyperplasia, Squamous Atypical, Five, Focal					1 (3%)	2 (6%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal						5 (14%)
Hyperplasia, Basal Cell						1 (3%)
Hyperplasia, Squamous	1 (3%)	7 (19%)			11 (31%)	24 (67%)
Dermis, Inflammation, Chronic Active	2 (6%)	2 (6%)			1 (3%)	15 (42%)
Epidermis, Inflammation, Suppurative						1 (3%)
Epidermis, Necrosis						2 (6%)
Epidermis, Ulcer						1 (3%)
Sebaceous Gland, Hyperplasia						

**MUSCULOSKELETAL SYSTEM**

None

**NERVOUS SYSTEM**

None

**RESPIRATORY SYSTEM**

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

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All-trans-retinyl palmitate

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Lab: NCTR

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
<b>Disposition Summary</b>						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed						
Moribund Sacrifice	1	1	1	3	1	3
Natural Death	1		1		1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice	4				2	1
Harvest	30	35	34	33	32	32
Animals Examined Microscopically	36	36				36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(0)	(0)	(0)	(36)
Abscess						
Cyst Epithelial Inclusion	3 (8%)	1 (3%)				1 (3%)
Edema						
Hyperplasia, Squamous Atypical, Focal	1 (3%)					
Hyperplasia, Squamous Ulcer		4 (11%)				1 (3%)
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active						1 (3%)
Epidermis, Inflammation, Suppurative						1 (3%)
Epidermis, Necrosis						
Epidermis, Ulcer						2 (6%)
Skin, Site Of Application	(36)	(36)	(0)	(0)	(0)	(36)
Abscess						
Cyst, Multiple						
Cyst Epithelial Inclusion	4 (11%)	1 (3%)				2 (6%)
Hyperplasia, Squamous Atypical, One, Focal	1 (3%)	8 (22%)				4 (11%)
Hyperplasia, Squamous Atypical, Two, Focal	4 (11%)	3 (8%)				4 (11%)
Hyperplasia, Squamous Atypical, Three, Focal	3 (8%)	2 (6%)				4 (11%)
Hyperplasia, Squamous Atypical, Four, Focal	6 (17%)	2 (6%)				5 (14%)
Hyperplasia, Squamous Atypical, Five, Focal	3 (8%)	3 (8%)				3 (8%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	14 (39%)	16 (44%)				13 (36%)
Hyperplasia, Basal Cell	1 (3%)					
Hyperplasia, Squamous	32 (89%)	36 (100%)				28 (78%)
Dermis, Inflammation, Chronic Active	28 (78%)	36 (100%)				12 (33%)
Epidermis, Inflammation, Suppurative	2 (6%)	7 (19%)				1 (3%)
Epidermis, Necrosis	4 (11%)	7 (19%)				2 (6%)
Epidermis, Ulcer	3 (8%)	9 (25%)				1 (3%)
Sebaceous Gland, Hyperplasia	1 (3%)					

**MUSCULOSKELETAL SYSTEM**

None

**NERVOUS SYSTEM**

None

**RESPIRATORY SYSTEM**

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
None						
<hr/> SPECIAL SENSES SYSTEM						
None						
<hr/> URINARY SYSTEM						
None						

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
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**Disposition Summary**

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed					1	
Moribund Sacrifice	3	2	2		4	1
Natural Death	1		2		1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	32	34	32	36	30	35
Animals Examined Microscopically	36	36	36			

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None



SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Abscess						
Cyst Epithelial Inclusion	4 (11%)	2 (6%)				
Edema			1 (3%)			
Hyperplasia, Squamous Atypical, Focal	1 (3%)					
Hyperplasia, Squamous	1 (3%)		6 (17%)			
Ulcer						
Dermis, Inflammation, Suppurative			1 (3%)			
Dermis, Inflammation, Chronic Active		1 (3%)	2 (6%)			
Epidermis, Inflammation, Suppurative						
Epidermis, Necrosis			1 (3%)			
Epidermis, Ulcer						
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Abscess						
Cyst, Multiple						
Cyst Epithelial Inclusion	9 (25%)	1 (3%)				
Hyperplasia, Squamous Atypical, One, Focal	5 (14%)	1 (3%)	3 (8%)			
Hyperplasia, Squamous Atypical, Two, Focal		1 (3%)	3 (8%)			
Hyperplasia, Squamous Atypical, Three, Focal	5 (14%)	6 (17%)	2 (6%)			
Hyperplasia, Squamous Atypical, Four, Focal	2 (6%)	4 (11%)	4 (11%)			
Hyperplasia, Squamous Atypical, Five, Focal	1 (3%)	5 (14%)	4 (11%)			
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	20 (56%)	19 (53%)	14 (39%)			
Hyperplasia, Basal Cell						
Hyperplasia, Squamous	33 (92%)	31 (86%)	35 (97%)			
Dermis, Inflammation, Chronic Active	18 (50%)	31 (86%)	33 (92%)			
Epidermis, Inflammation, Suppurative	3 (8%)	3 (8%)	9 (25%)			
Epidermis, Necrosis	3 (8%)	5 (14%)	14 (39%)			
Epidermis, Ulcer	2 (6%)	3 (8%)	6 (17%)			
Sebaceous Gland, Hyperplasia						

**MUSCULOSKELETAL SYSTEM**

None

**NERVOUS SYSTEM**

None

**RESPIRATORY SYSTEM**

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None						
<hr/> SPECIAL SENSES SYSTEM						
None						
<hr/> URINARY SYSTEM						
None						

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F
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### Disposition Summary

Animals Initially in Study	36	36
Early Deaths		
Accidently Killed		
Moribund Sacrifice		5
Natural Death		1
Survivors		
Moribund Sacrifice		1
Terminal Sacrifice		9
Harvest	36	20
Animals Examined Microscopically	36	

#### ALIMENTARY SYSTEM

None

#### CARDIOVASCULAR SYSTEM

None

#### ENDOCRINE SYSTEM

None

#### GENERAL BODY SYSTEM

None

#### GENITAL SYSTEM

None

#### HEMATOPOIETIC SYSTEM

None

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F
<b>INTEGUMENTARY SYSTEM</b>		
Skin, Control	(36)	(0)
Abscess	1 (3%)	
Cyst Epithelial Inclusion	4 (11%)	
Edema		
Hyperplasia, Squamous Atypical, Focal		
Hyperplasia, Squamous Ulcer	1 (3%)	
Dermis, Inflammation, Suppurative		
Dermis, Inflammation, Chronic Active		
Epidermis, Inflammation, Suppurative		
Epidermis, Necrosis		
Epidermis, Ulcer		
Skin, Site Of Application	(36)	(0)
Abscess	1 (3%)	
Cyst, Multiple		
Cyst Epithelial Inclusion	2 (6%)	
Hyperplasia, Squamous Atypical, One, Focal	4 (11%)	
Hyperplasia, Squamous Atypical, Two, Focal	9 (25%)	
Hyperplasia, Squamous Atypical, Three, Focal	7 (19%)	
Hyperplasia, Squamous Atypical, Four, Focal	7 (19%)	
Hyperplasia, Squamous Atypical, Five, Focal	4 (11%)	
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	4 (11%)	
Hyperplasia, Basal Cell		
Hyperplasia, Squamous	28 (78%)	
Dermis, Inflammation, Chronic Active	21 (58%)	
Epidermis, Inflammation, Suppurative	3 (8%)	
Epidermis, Necrosis	1 (3%)	
Epidermis, Ulcer	4 (11%)	
Sebaceous Gland, Hyperplasia		

**MUSCULOSKELETAL SYSTEM**

None

**NERVOUS SYSTEM**

None

**RESPIRATORY SYSTEM**

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SKH-1 HAIRLESS MICE (NCTR) MICE  
FEMALE

NOCREAMF20.55SSL

1% RP NO SSL-F

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None

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SPECIAL SENSES SYSTEM

None

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URINARY SYSTEM

None

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