

**TDMS No.** 20117 - 02

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

**Date Report Requested:** 06/29/2009

**Test Type:** 1-YEAR

All-trans-retinyl palmitate

**Time Report Requested:** 16:32:02

**Route:** SKIN APPLICATION

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

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

**Species/Strain:** MICE/SKH-1/NCTR

**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

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

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

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)

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Lab: NCTR

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						
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(0)	(0)	(36)	(36)
Abscess	1 [3.0]				1 [4.0]	
Cyst Epithelial Inclusion	2	4			4	6
Edema						
Hyperplasia, Squamous Atypical, Focal						
Hyperplasia, Squamous	1 [2.0]					1 [4.0]
Ulcer		1 [3.0]				
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active	3 [3.0]	1 [3.0]			1 [4.0]	1 [3.0]
Epidermis, Inflammation, Suppurative						
Epidermis, Necrosis						
Epidermis, Ulcer	1 [3.0]					
Skin, Site Of Application	(36)	(36)	(0)	(0)	(36)	(36)
Abscess	1 [4.0]	1 [4.0]				1 [3.0]
Cyst, Multiple	1					
Cyst Epithelial Inclusion	2				4	5
Hyperplasia, Squamous Atypical, One, Focal					11	6
Hyperplasia, Squamous Atypical, Two, Focal		1			1	5
Hyperplasia, Squamous Atypical, Three, Focal					2	6
Hyperplasia, Squamous Atypical, Four, Focal					1	3
Hyperplasia, Squamous Atypical, Five, Focal					1	2
Hyperplasia, Squamous Atypical, Greater Than Five, Focal						5
Hyperplasia, Basal Cell						1 [2.0]
Hyperplasia, Squamous	1 [1.0]	7 [1.1]			11 [1.3]	24 [1.8]
Dermis, Inflammation, Chronic Active	2 [1.5]	2 [1.5]			1 [3.0]	15 [1.7]
Epidermis, Inflammation, Suppurative						1 [1.0]
Epidermis, Necrosis						2 [1.0]
Epidermis, Ulcer						1 [1.0]
Sebaceous Gland, Hyperplasia						

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: 1-YEAR

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Lab: NCTR

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
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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)

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

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

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)

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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 CREAM13.75SSLF
None						
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(0)	(0)	(0)	(36)
Abscess						
Cyst Epithelial Inclusion	3	1				1
Edema						
Hyperplasia, Squamous Atypical, Focal	1					
Hyperplasia, Squamous		4 [1.5]				1 [1.0]
Ulcer						
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active						1 [4.0]
Epidermis, Inflammation, Suppurative						1 [4.0]
Epidermis, Necrosis						
Epidermis, Ulcer						2 [4.0]
Skin, Site Of Application	(36)	(36)	(0)	(0)	(0)	(36)
Abscess						
Cyst, Multiple						
Cyst Epithelial Inclusion	4	1				2
Hyperplasia, Squamous Atypical, One, Focal	1	8				4
Hyperplasia, Squamous Atypical, Two, Focal	4	3				4
Hyperplasia, Squamous Atypical, Three, Focal	3	2				4
Hyperplasia, Squamous Atypical, Four, Focal	6	2				5
Hyperplasia, Squamous Atypical, Five, Focal	3	3				3
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	14	16				13
Hyperplasia, Basal Cell	1 [3.0]					
Hyperplasia, Squamous	32 [2.0]	36 [2.5]				28 [1.5]
Dermis, Inflammation, Chronic Active	28 [1.9]	36 [2.0]				12 [1.6]
Epidermis, Inflammation, Suppurative	2 [2.5]	7 [1.9]				1 [2.0]
Epidermis, Necrosis	4 [1.8]	7 [1.6]				2 [1.5]
Epidermis, Ulcer	3 [3.3]	9 [2.6]				1 [3.0]
Sebaceous Gland, Hyperplasia	1 [3.0]					

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)

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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
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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)

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Lab: NCTR

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>Disposition Summary</b>						
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

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)



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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
None						
<b>INTEGUMENTARY SYSTEM</b>						
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Abscess						
Cyst Epithelial Inclusion	4	2				
Edema			1 [4.0]			
Hyperplasia, Squamous Atypical, Focal	1					
Hyperplasia, Squamous Ulcer	1 [2.0]		6 [1.3]			
Dermis, Inflammation, Suppurative			1 [3.0]			
Dermis, Inflammation, Chronic Active		1 [3.0]	2 [2.0]			
Epidermis, Inflammation, Suppurative						
Epidermis, Necrosis			1 [2.0]			
Epidermis, Ulcer						
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Abscess						
Cyst, Multiple						
Cyst Epithelial Inclusion	9	1				
Hyperplasia, Squamous Atypical, One, Focal	5	1	3			
Hyperplasia, Squamous Atypical, Two, Focal		1	3			
Hyperplasia, Squamous Atypical, Three, Focal	5	6	2			
Hyperplasia, Squamous Atypical, Four, Focal	2	4	4			
Hyperplasia, Squamous Atypical, Five, Focal	1	5	4			
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	20	19	14			
Hyperplasia, Basal Cell						
Hyperplasia, Squamous	33 [1.9]	31 [2.5]	35 [2.9]			
Dermis, Inflammation, Chronic Active	18 [1.8]	31 [1.9]	33 [2.4]			
Epidermis, Inflammation, Suppurative	3 [2.0]	3 [3.7]	9 [2.3]			
Epidermis, Necrosis	3 [1.3]	5 [2.0]	14 [2.1]			
Epidermis, Ulcer	2 [3.0]	3 [3.7]	6 [3.2]			
Sebaceous Gland, Hyperplasia						

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

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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
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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)

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Lab: NCTR

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

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)

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F
None		

INTEGUMENTARY SYSTEM

Skin, Control	(36)	(0)
Abscess	1 [4.0]	
Cyst Epithelial Inclusion	4	
Edema		
Hyperplasia, Squamous Atypical, Focal		
Hyperplasia, Squamous Ulcer	1 [2.0]	
Dermis, Inflammation, Suppurative		
Dermis, Inflammation, Chronic Active		
Epidermis, Inflammation, Suppurative		
Epidermis, Necrosis		
Epidermis, Ulcer		
Skin, Site Of Application	(36)	(0)
Abscess	1 [3.0]	
Cyst, Multiple		
Cyst Epithelial Inclusion	2	
Hyperplasia, Squamous Atypical, One, Focal	4	
Hyperplasia, Squamous Atypical, Two, Focal	9	
Hyperplasia, Squamous Atypical, Three, Focal	7	
Hyperplasia, Squamous Atypical, Four, Focal	7	
Hyperplasia, Squamous Atypical, Five, Focal	4	
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	4	
Hyperplasia, Basal Cell		
Hyperplasia, Squamous	28 [1.8]	
Dermis, Inflammation, Chronic Active	21 [1.9]	
Epidermis, Inflammation, Suppurative	3 [2.7]	
Epidermis, Necrosis	1 [2.0]	
Epidermis, Ulcer	4 [3.5]	
Sebaceous Gland, Hyperplasia		

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

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SKH-1 HAIRLESS MICE (NCTR) MICE  
FEMALE

NOCREAMF20.55SSL 1% RP NO SSL-F

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MUSCULOSKELETAL SYSTEM

None

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NERVOUS SYSTEM

None

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RESPIRATORY SYSTEM

None

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SPECIAL SENSES SYSTEM

None

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URINARY SYSTEM

None

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