

TDMS No. 20117 - 01

**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: 16:29:37

Route: SKIN APPLICATION

CAS Number: 79-81-2

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

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: Male
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 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
Disposition Summary						
Animals Initially in Study	34	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	5	3	7	2	8	7
Natural Death	1	2	2		1	1
Survivors						
Moribund Sacrifice	1			1		
Terminal Sacrifice	27	29	3	20	25	1
Harvest		2	24	13	2	27
Animals Examined Microscopically	34	36			35	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC 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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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
INTEGUMENTARY SYSTEM						
Skin, Control	(34)	(36)	(0)	(0)	(35)	(36)
Abscess		4 [4.0]			2 [4.0]	1 [4.0]
Cyst Epithelial Inclusion	2	2			6	6
Hyperplasia, Squamous	1 [2.0]					1 [3.0]
Infiltration Cellular, Lymphocyte						
Inflammation, Suppurative					1 [4.0]	
Necrosis					1 [4.0]	
Ulcer						
Dermis, Inflammation, Suppurative		1 [3.0]				
Dermis, Inflammation, Chronic Active		1 [3.0]				2 [3.5]
Epidermis, Inflammation, Suppurative	1 [2.0]					1 [3.0]
Epidermis, Necrosis						1 [3.0]
Epidermis, Ulcer		1 [4.0]				
Skin, Site Of Application	(34)	(36)	(0)	(0)	(35)	(36)
Abscess						1 [4.0]
Cyst Epithelial Inclusion	3	5			4	6
Hyperplasia, Squamous Atypical, One, Focal		4			5	2
Hyperplasia, Squamous Atypical, Two, Focal					1	2
Hyperplasia, Squamous Atypical, Three, Focal						5
Hyperplasia, Squamous Atypical, Four, Focal					1	3
Hyperplasia, Squamous Atypical, Five, Focal					2	2
Hyperplasia, Squamous Atypical, Greater Than Five, Focal						14
Hyperplasia, Squamous Keratin Cyst		6 [1.5]			4 [2.0]	23 [2.0]
Dermis, Inflammation, Chronic Active		3 [2.0]			3 [2.0]	9 [1.4]
Epidermis, Inflammation, Suppurative					1 [1.0]	
Epidermis, Necrosis					1 [1.0]	3 [1.3]
Epidermis, Ulcer		1 [2.0]			1 [2.0]	
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)

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Species/Strain: MICE/SKH-1/NCTR

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
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 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	3	3	1	4	1	
Natural Death				2		1
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	33	32	35	30	35	35
Animals Examined Microscopically	36	35				36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC 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 MALE	.1% RP 6.75SSL M	.5% RP 6.75SSL M	1% RP 6.75SSL M	2% RP 6.75SSL M	.001% RA6.75SSL M	NO CREAM13.7SSL M
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(35)	(0)	(0)	(0)	(36)
Abscess	4 [4.0]					2 [3.5]
Cyst Epithelial Inclusion	1	1				3
Hyperplasia, Squamous						3 [2.7]
Infiltration Cellular, Lymphocyte						
Inflammation, Suppurative						1 [4.0]
Necrosis						
Ulcer						
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active	1 [3.0]					4 [2.8]
Epidermis, Inflammation, Suppurative	1 [3.0]					1 [3.0]
Epidermis, Necrosis						
Epidermis, Ulcer	1 [3.0]					1 [4.0]
Skin, Site Of Application	(36)	(35)	(0)	(0)	(0)	(36)
Abscess						
Cyst Epithelial Inclusion						3
Hyperplasia, Squamous Atypical, One, Focal	3	1				3
Hyperplasia, Squamous Atypical, Two, Focal	2					6
Hyperplasia, Squamous Atypical, Three, Focal		2				5
Hyperplasia, Squamous Atypical, Four, Focal	2	2				5
Hyperplasia, Squamous Atypical, Five, Focal	5	3				3
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	21	23				10
Hyperplasia, Squamous	32 [2.1]	34 [2.4]				26 [1.7]
Keratin Cyst						
Dermis, Inflammation, Chronic Active	12 [1.6]	30 [1.7]				5 [1.6]
Epidermis, Inflammation, Suppurative	7 [1.3]	8 [2.3]				1 [3.0]
Epidermis, Necrosis	9 [1.7]	14 [1.8]				3 [1.7]
Epidermis, Ulcer	7 [2.1]	8 [2.5]				1 [4.0]
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)

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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
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 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
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Disposition Summary

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	3	1		2	1	
Natural Death			1	1	1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	33	35	35	33	34	36
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

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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INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Abscess	2 [4.0]	2 [3.5]				
Cyst Epithelial Inclusion	2	2	2			
Hyperplasia, Squamous		1 [3.0]	2 [1.5]			
Infiltration Cellular, Lymphocyte						
Inflammation, Suppurative		1 [4.0]	1 [4.0]			
Necrosis						
Ulcer		1 [4.0]				
Dermis, Inflammation, Suppurative						
Dermis, Inflammation, Chronic Active	2 [3.5]	3 [3.3]	2 [2.0]			
Epidermis, Inflammation, Suppurative	2 [3.5]					
Epidermis, Necrosis						
Epidermis, Ulcer	2 [3.5]	2 [4.0]	1 [4.0]			
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Abscess			2 [4.0]			
Cyst Epithelial Inclusion	3	1	1			
Hyperplasia, Squamous Atypical, One, Focal		1				
Hyperplasia, Squamous Atypical, Two, Focal		2	2			
Hyperplasia, Squamous Atypical, Three, Focal	7	4	2			
Hyperplasia, Squamous Atypical, Four, Focal		3	3			
Hyperplasia, Squamous Atypical, Five, Focal	2	2	2			
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	24	24	26			
Hyperplasia, Squamous	27 [2.0]	34 [2.6]	35 [3.1]			
Keratin Cyst	1					
Dermis, Inflammation, Chronic Active	8 [2.1]	20 [2.0]	32 [1.9]			
Epidermis, Inflammation, Suppurative	3 [1.3]	7 [2.4]	14 [1.9]			
Epidermis, Necrosis	5 [1.8]	11 [1.6]	20 [2.2]			
Epidermis, Ulcer	3 [1.7]	8 [3.0]	10 [2.5]			
Sebaceous Gland, Hyperplasia	1 [2.0]	1 [2.0]				

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 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
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 MALE NOCREAMM20.55SSL 1% RP NO SSL-M

Disposition Summary

Animals Initially in Study	36	36
Early Deaths		
Moribund Sacrifice	1	7
Natural Death	1	1
Survivors		
Moribund Sacrifice		
Terminal Sacrifice		8
Harvest	34	20
Animals Examined Microscopically	36	

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE NOCREAMM20.55SSL 1% RP NO SSL-M

INTEGUMENTARY SYSTEM

Skin, Control	(36)	(0)
Abscess	1 [4.0]	
Cyst Epithelial Inclusion	2	
Hyperplasia, Squamous	2 [2.0]	
Infiltration Cellular, Lymphocyte	1 [3.0]	
Inflammation, Suppurative		
Necrosis		
Ulcer		
Dermis, Inflammation, Suppurative		
Dermis, Inflammation, Chronic Active	4 [2.5]	
Epidermis, Inflammation, Suppurative	2 [3.0]	
Epidermis, Necrosis	1 [2.0]	
Epidermis, Ulcer	3 [2.3]	
Skin, Site Of Application	(36)	(0)
Abscess		
Cyst Epithelial Inclusion		
Hyperplasia, Squamous Atypical, One, Focal	2	
Hyperplasia, Squamous Atypical, Two, Focal	3	
Hyperplasia, Squamous Atypical, Three, Focal	8	
Hyperplasia, Squamous Atypical, Four, Focal	4	
Hyperplasia, Squamous Atypical, Five, Focal	4	
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	9	
Hyperplasia, Squamous	18 [1.6]	
Keratin Cyst		
Dermis, Inflammation, Chronic Active	8 [1.6]	
Epidermis, Inflammation, Suppurative	1 [2.0]	
Epidermis, Necrosis	2 [1.0]	
Epidermis, Ulcer	1 [4.0]	
Sebaceous Gland, Hyperplasia	1 [2.0]	

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE NOCREAMM20.55SSL 1% RP NO SSL-M

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

*** END OF MALE ***

*** END OF REPORT ***

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)