

TDMS No. 20406 - 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)

ALOE PHOTOTOXICITY STUDIES
CAS Number: ALOEPHOTOTOX
Pathologist: MELLICK, P.

Date Report Requested: 09/21/2006
Time Report Requested: 08:30:21
First Dose M/F: 05/11/03 / NA
Lab: NCTR

C Number: C20406
Lock Date: Not Entered.
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL
Disposition Summary					
Animals Initially in Study	36	35	36	36	36
Early Deaths					
Accidentally Killed			1		
Moribund Sacrifice		5	1	4	3
Natural Death	1			1	2
Survivors					
Moribund Sacrifice				1	
Natural Death					
Terminal Sacrifice	35	30	34	30	30
Harvest					1
Animals Examined Microscopically	36	35	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

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Pathologist: MELLICK, P.

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(36)	(35)	(36)	(35)	(36)
Abscess					
Cyst Epithelial Inclusion	2 (6%)	3 (9%)	1 (3%)	3 (9%)	4 (11%)
Developmental Malformation					
Granuloma					
Hyperplasia, Squamous Atypical, One, Focal					
Hyperplasia, Squamous	2 (6%)	2 (6%)	2 (6%)	1 (3%)	1 (3%)
Inflammation, Pyogranulomatous	3 (8%)		3 (8%)	3 (9%)	3 (8%)
Dermis, Inflammation, Chronic Active	34 (94%)	31 (89%)	34 (94%)	32 (91%)	36 (100%)
Epidermis, Necrosis	2 (6%)		1 (3%)	1 (3%)	1 (3%)
Subcutaneous Tissue, Edema					
Skin, Site Of Application	(36)	(35)	(36)	(35)	(36)
Abscess					
Cyst Epithelial Inclusion	1 (3%)	2 (6%)	4 (11%)	3 (9%)	5 (14%)
Granuloma				1 (3%)	
Hyperplasia, Squamous Atypical, One, Focal					
Hyperplasia, Squamous Atypical, Two, Focal					
Hyperplasia, Squamous Atypical, Three, Focal					
Hyperplasia, Squamous Atypical, Four, Focal					
Hyperplasia, Squamous Atypical, Five, Focal					
Hyperplasia, Squamous Atypical, Greater Than Five, Focal					
Hyperplasia, Squamous	1 (3%)	1 (3%)	1 (3%)		1 (3%)
Inflammation, Pyogranulomatous					1 (3%)
Dermis, Inflammation, Chronic Active	36 (100%)	33 (94%)	36 (100%)	34 (97%)	36 (100%)
Epidermis, Necrosis		1 (3%)			1 (3%)
Subcutaneous Tissue, Inflammation, Pyogranulomatous					

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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

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Species/Strain: MICE/SKH-1/NCTR

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL
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

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_HI NO_SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
Disposition Summary					
Animals Initially in Study	35	36	36	36	36
Early Deaths					
Accidently Killed		1			
Moribund Sacrifice	7	5		3	5
Natural Death		2		1	
Survivors					
Moribund Sacrifice		1			
Natural Death					
Terminal Sacrifice	27	22			
Harvest	1	5	36	31	31
Animals Examined Microscopically	35	36	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

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_HI NO_SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(35)	(36)	(36)	(35)	(36)
Abscess		2 (6%)	1 (3%)		1 (3%)
Cyst Epithelial Inclusion	3 (9%)	4 (11%)	4 (11%)	4 (11%)	3 (8%)
Developmental Malformation					1 (3%)
Granuloma					
Hyperplasia, Squamous Atypical, One, Focal			2 (6%)	2 (6%)	
Hyperplasia, Squamous Inflammation, Pyogranulomatous			4 (11%)		2 (6%)
Dermis, Inflammation, Chronic Active	32 (91%)	30 (83%)	22 (61%)	30 (86%)	26 (72%)
Epidermis, Necrosis			1 (3%)	1 (3%)	3 (8%)
Subcutaneous Tissue, Edema		1 (3%)			
Skin, Site Of Application	(35)	(36)	(36)	(35)	(36)
Abscess		1 (3%)			
Cyst Epithelial Inclusion	9 (26%)	12 (33%)	5 (14%)	3 (9%)	7 (19%)
Granuloma					
Hyperplasia, Squamous Atypical, One, Focal	1 (3%)	6 (17%)	5 (14%)	5 (14%)	2 (6%)
Hyperplasia, Squamous Atypical, Two, Focal		3 (8%)	9 (25%)	6 (17%)	10 (28%)
Hyperplasia, Squamous Atypical, Three, Focal		1 (3%)	6 (17%)	7 (20%)	5 (14%)
Hyperplasia, Squamous Atypical, Four, Focal		1 (3%)	3 (8%)	4 (11%)	4 (11%)
Hyperplasia, Squamous Atypical, Five, Focal		1 (3%)	2 (6%)	5 (14%)	3 (8%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal			8 (22%)	4 (11%)	4 (11%)
Hyperplasia, Squamous Inflammation, Pyogranulomatous	1 (3%)	20 (56%)	35 (97%)	31 (89%)	33 (92%)
Dermis, Inflammation, Chronic Active	33 (94%)	33 (92%)	34 (94%)	32 (91%)	32 (89%)
Epidermis, Necrosis					2 (6%)
Subcutaneous Tissue, Inflammation, Pyogranulomatous			1 (3%)		

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL
Disposition Summary					
Animals Initially in Study	36	36	36	36	36
Early Deaths					
Accidently Killed					
Moribund Sacrifice	1	1	2	2	4
Natural Death		2	1	1	
Survivors					
Moribund Sacrifice					
Natural Death					
Terminal Sacrifice		1	1		
Harvest	35	32	32	33	32
Animals Examined Microscopically	36	36	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

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(36)	(36)	(36)	(36)	(36)
Abscess		1 (3%)			1 (3%)
Cyst Epithelial Inclusion	3 (8%)		3 (8%)	2 (6%)	4 (11%)
Developmental Malformation					
Granuloma	2 (6%)				1 (3%)
Hyperplasia, Squamous Atypical, One, Focal	1 (3%)				
Hyperplasia, Squamous	2 (6%)	3 (8%)		1 (3%)	1 (3%)
Inflammation, Pyogranulomatous		3 (8%)	3 (8%)		1 (3%)
Dermis, Inflammation, Chronic Active	30 (83%)	31 (86%)	30 (83%)	27 (75%)	33 (92%)
Epidermis, Necrosis	1 (3%)		4 (11%)	2 (6%)	
Subcutaneous Tissue, Edema					
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)
Abscess			1 (3%)		
Cyst Epithelial Inclusion	4 (11%)	6 (17%)	2 (6%)	5 (14%)	4 (11%)
Granuloma			1 (3%)		
Hyperplasia, Squamous Atypical, One, Focal	4 (11%)	4 (11%)	4 (11%)	4 (11%)	5 (14%)
Hyperplasia, Squamous Atypical, Two, Focal	10 (28%)	5 (14%)	5 (14%)	14 (39%)	2 (6%)
Hyperplasia, Squamous Atypical, Three, Focal	6 (17%)	4 (11%)	12 (33%)	9 (25%)	4 (11%)
Hyperplasia, Squamous Atypical, Four, Focal	4 (11%)	7 (19%)	4 (11%)		10 (28%)
Hyperplasia, Squamous Atypical, Five, Focal	5 (14%)	4 (11%)	1 (3%)	3 (8%)	4 (11%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	5 (14%)	5 (14%)	8 (22%)	4 (11%)	5 (14%)
Hyperplasia, Squamous	36 (100%)	34 (94%)	34 (94%)	35 (97%)	35 (97%)
Inflammation, Pyogranulomatous	1 (3%)	1 (3%)			
Dermis, Inflammation, Chronic Active	34 (94%)	32 (89%)	33 (92%)	34 (94%)	34 (94%)
Epidermis, Necrosis	3 (8%)	2 (6%)	2 (6%)	6 (17%)	5 (14%)
Subcutaneous Tissue, Inflammation, Pyogranulomatous					

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL
None					
<hr/> RESPIRATORY SYSTEM					
None					
<hr/> SPECIAL SENSES SYSTEM					
None					
<hr/> URINARY SYSTEM					
None					

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
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Disposition Summary

Animals Initially in Study	35	36	36
Early Deaths			
Accidentally Killed			
Moribund Sacrifice	3		3
Natural Death	2	1	
Survivors			
Moribund Sacrifice			
Natural Death			
Terminal Sacrifice		1	
Harvest	30	34	33
Animals Examined Microscopically	35	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

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
INTEGUMENTARY SYSTEM			
Skin, Control	(34)	(36)	(36)
Abscess		1 (3%)	1 (3%)
Cyst Epithelial Inclusion	2 (6%)	6 (17%)	1 (3%)
Developmental Malformation			
Granuloma			
Hyperplasia, Squamous Atypical, One, Focal			
Hyperplasia, Squamous	1 (3%)	1 (3%)	
Inflammation, Pyogranulomatous	4 (12%)	2 (6%)	1 (3%)
Dermis, Inflammation, Chronic Active	28 (82%)	34 (94%)	20 (56%)
Epidermis, Necrosis	5 (15%)	1 (3%)	1 (3%)
Subcutaneous Tissue, Edema			
Skin, Site Of Application	(35)	(36)	(36)
Abscess			1 (3%)
Cyst Epithelial Inclusion	3 (9%)	2 (6%)	1 (3%)
Granuloma			
Hyperplasia, Squamous Atypical, One, Focal	5 (14%)	8 (22%)	7 (19%)
Hyperplasia, Squamous Atypical, Two, Focal	5 (14%)	5 (14%)	9 (25%)
Hyperplasia, Squamous Atypical, Three, Focal	5 (14%)	4 (11%)	3 (8%)
Hyperplasia, Squamous Atypical, Four, Focal	8 (23%)	4 (11%)	6 (17%)
Hyperplasia, Squamous Atypical, Five, Focal	3 (9%)	5 (14%)	2 (6%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	4 (11%)	7 (19%)	5 (14%)
Hyperplasia, Squamous	32 (91%)	32 (89%)	28 (78%)
Inflammation, Pyogranulomatous	2 (6%)		
Dermis, Inflammation, Chronic Active	35 (100%)	32 (89%)	26 (72%)
Epidermis, Necrosis	7 (20%)	1 (3%)	5 (14%)
Subcutaneous Tissue, Inflammation, Pyogranulomatous			

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
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None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

*** END OF MALE ***

*** END OF REPORT ***