

**TDMS No.** 20406 - 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)**

Aloe phototoxicity studies

**CAS Number:** ALOEPHOTOTOX

**Date Report Requested:** 09/06/2007

**Time Report Requested:** 15:58:56

**First Dose M/F:** NA / 05/11/03

**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

**TDMSE Version:** 1.8.0

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
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**Disposition Summary**

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	5	7	2	2	3	
Natural Death	1		2			1
Survivors						
Moribund Sacrifice			2		1	2
Terminal Sacrifice	30	28	30	33	32	33
Harvest		1		1		
Animals Examined Microscopically	36	36	36	36	36	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

INTEGUMENTARY SYSTEM

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess		2 (6%)	1 (3%)			1 (3%)
Cyst Epithelial Inclusion	3 (8%)	6 (17%)	3 (8%)	3 (8%)	4 (11%)	1 (3%)
Edema		1 (3%)			1 (3%)	
Hemorrhage		1 (3%)				
Hyperplasia, Squamous Atypical, One, Focal						
Hyperplasia, Squamous	1 (3%)	5 (14%)	1 (3%)	4 (11%)		
Inflammation, Pyogranulomatous		1 (3%)		1 (3%)		2 (6%)
Dermis, Inflammation, Granulomatous						
Dermis, Inflammation, Chronic Active	32 (89%)	32 (89%)	35 (97%)	36 (100%)	34 (94%)	36 (100%)
Epidermis, Necrosis						
Subcutaneous Tissue, Abscess						1 (3%)
Subcutaneous Tissue, Inflammation, Chronic						
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)	(36)
Abscess		1 (3%)				
Cyst						
Cyst Epithelial Inclusion	3 (8%)		2 (6%)	2 (6%)	5 (14%)	6 (17%)
Edema					1 (3%)	
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%)	10 (28%)	13 (36%)	2 (6%)	1 (3%)	2 (6%)
Inflammation, Pyogranulomatous						
Dermis, Inflammation, Chronic Active	33 (92%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)
Epidermis, Necrosis						

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

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

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_H NO_ SSL
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
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**Disposition Summary**

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	1	1	1	4	4	2
Natural Death	1				1	1
Survivors						
Moribund Sacrifice	3					1
Terminal Sacrifice	24	1	2			1
Harvest	7	34	33	32	31	31
Animals Examined Microscopically	36	36	36	36	36	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

INTEGUMENTARY SYSTEM

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess					3 (8%)	
Cyst Epithelial Inclusion	7 (19%)	3 (8%)	3 (8%)	5 (14%)	5 (14%)	4 (11%)
Edema						
Hemorrhage		1 (3%)				
Hyperplasia, Squamous Atypical, One, Focal			1 (3%)	1 (3%)	1 (3%)	1 (3%)
Hyperplasia, Squamous	1 (3%)	12 (33%)	3 (8%)			
Inflammation, Pyogranulomatous		1 (3%)		3 (8%)		
Dermis, Inflammation, Granulomatous						
Dermis, Inflammation, Chronic Active	35 (97%)	29 (81%)	29 (81%)	30 (83%)	35 (97%)	32 (89%)
Epidermis, Necrosis		1 (3%)		2 (6%)		
Subcutaneous Tissue, Abscess			1 (3%)			
Subcutaneous Tissue, Inflammation, Chronic		1 (3%)				
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)	(36)
Abscess						
Cyst			1 (3%)			
Cyst Epithelial Inclusion	6 (17%)	5 (14%)	5 (14%)	10 (28%)	5 (14%)	8 (22%)
Edema						
Granuloma			1 (3%)		1 (3%)	
Hyperplasia, Squamous Atypical, One, Focal	10 (28%)	7 (19%)	8 (22%)	10 (28%)	10 (28%)	6 (17%)
Hyperplasia, Squamous Atypical, Two, Focal	2 (6%)	8 (22%)	4 (11%)	8 (22%)	5 (14%)	10 (28%)
Hyperplasia, Squamous Atypical, Three, Focal	1 (3%)	8 (22%)	7 (19%)	3 (8%)	5 (14%)	5 (14%)
Hyperplasia, Squamous Atypical, Four, Focal		3 (8%)	7 (19%)	3 (8%)	3 (8%)	4 (11%)
Hyperplasia, Squamous Atypical, Five, Focal	1 (3%)	1 (3%)	4 (11%)	1 (3%)	4 (11%)	6 (17%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	1 (3%)	5 (14%)	5 (14%)	2 (6%)	2 (6%)	2 (6%)
Hyperplasia, Squamous	32 (89%)	36 (100%)	35 (97%)	34 (94%)	33 (92%)	35 (97%)
Inflammation, Pyogranulomatous		2 (6%)	1 (3%)			2 (6%)
Dermis, Inflammation, Chronic Active	36 (100%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)	35 (97%)
Epidermis, Necrosis			1 (3%)	3 (8%)		1 (3%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

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Species/Strain: MICE/SKH-1/NCTR

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

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CAS Number: ALOEPHOTOTOX

Date Report Requested: 09/06/2007

Time Report Requested: 15:58:56

First Dose M/F: NA / 05/11/03

Lab: NCTR

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
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SPECIAL SENSES SYSTEM

None

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URINARY SYSTEM

None

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
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**Disposition Summary**

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	1		2	4	1	1
Natural Death	3	2	1		2	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	32	34	33	32	33	35
Animals Examined Microscopically	36	36	36	36	36	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

INTEGUMENTARY SYSTEM



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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess				1 (3%)		
Cyst Epithelial Inclusion	3 (8%)	5 (14%)	2 (6%)	3 (8%)	1 (3%)	1 (3%)
Edema						
Hemorrhage	1 (3%)					
Hyperplasia, Squamous Atypical, One, Focal			1 (3%)	1 (3%)	1 (3%)	
Hyperplasia, Squamous	1 (3%)		4 (11%)			
Inflammation, Pyogranulomatous		1 (3%)	1 (3%)		1 (3%)	
Dermis, Inflammation, Granulomatous	1 (3%)					
Dermis, Inflammation, Chronic Active	30 (83%)	33 (92%)	29 (81%)	31 (86%)	30 (83%)	19 (53%)
Epidermis, Necrosis		1 (3%)				
Subcutaneous Tissue, Abscess						
Subcutaneous Tissue, Inflammation, Chronic						
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)	(36)
Abscess						
Cyst						
Cyst Epithelial Inclusion	1 (3%)	7 (19%)	5 (14%)	5 (14%)		2 (6%)
Edema						
Granuloma	2 (6%)					
Hyperplasia, Squamous Atypical, One, Focal	5 (14%)	12 (33%)	6 (17%)	8 (22%)	6 (17%)	5 (14%)
Hyperplasia, Squamous Atypical, Two, Focal	7 (19%)	9 (25%)	6 (17%)	5 (14%)	5 (14%)	6 (17%)
Hyperplasia, Squamous Atypical, Three, Focal	6 (17%)	9 (25%)	3 (8%)	8 (22%)	5 (14%)	5 (14%)
Hyperplasia, Squamous Atypical, Four, Focal	6 (17%)	1 (3%)	4 (11%)	6 (17%)	5 (14%)	7 (19%)
Hyperplasia, Squamous Atypical, Five, Focal	3 (8%)		1 (3%)	3 (8%)	4 (11%)	4 (11%)
Hyperplasia, Squamous Atypical, Greater Than Five, Focal	2 (6%)	1 (3%)	7 (19%)	2 (6%)	2 (6%)	7 (19%)
Hyperplasia, Squamous	32 (89%)	34 (94%)	35 (97%)	34 (94%)	34 (94%)	34 (94%)
Inflammation, Pyogranulomatous			2 (6%)	1 (3%)		
Dermis, Inflammation, Chronic Active	33 (92%)	35 (97%)	33 (92%)	35 (97%)	35 (97%)	32 (89%)
Epidermis, Necrosis		4 (11%)	3 (8%)	1 (3%)	1 (3%)	3 (8%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

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SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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