

**TDMS No.** 20406 - 01  
**Test Type:** 1-YEAR  
**Route:** SKIN APPLICATION  
**Species/Strain:** MICE/SKH-1/NCTR

**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**  
ALOE PHOTOTOXICITY STUDIES  
**CAS Number:** ALOEPHOTOTOX  
**Pathologist:** MELLICK, P.

**Date Report Reqsted:** 09/21/2006  
**Time Report Reqsted:** 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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 ALOE PHOTOTOXICITY STUDIES  
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Date Report Requested: 09/21/2006  
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 First Dose M/F: 05/11/03 / NA  
 Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL
<b>Disposition Summary</b>					
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

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	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL
None					
<b>INTEGUMENTARY SYSTEM</b>					
Skin, Control	(36)	(35)	(36)	(35)	(36)
Squamous Cell Carcinoma, One					
Squamous Cell Papilloma, One					
Subcutaneous Tissue, Mast Cell Tumor					
Malignant					
Skin, Site Of Application	(36)	(35)	(36)	(35)	(36)
Basal Cell Carcinoma, One					
Fibrosarcoma					
Lymphoma Malignant					
Squamous Cell Carcinoma, One					
Squamous Cell Carcinoma, Two					
Squamous Cell Carcinoma, Three					
Squamous Cell Carcinoma, Four					
Squamous Cell Carcinoma, Greater Than Five					
Squamous Cell Carcinoma In Situ, One					
Squamous Cell Carcinoma In Situ, Two					
Squamous Cell Carcinoma In Situ, Three					
Squamous Cell Carcinoma In Situ, Four					
Squamous Cell Carcinoma In Situ, Five					
Squamous Cell Carcinoma In Situ, Greater Than Five					
Squamous Cell Papilloma, One					
Squamous Cell Papilloma, Two					
Squamous Cell Papilloma, Three					
Squamous Cell Papilloma, Four					
Squamous Cell Papilloma, Five					
Squamous Cell Papilloma, Greater Than Five					
Sebaceous Gland, Adenoma, One			1 (3%)		
<b>MUSCULOSKELETAL SYSTEM</b>					
None					

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

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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
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					
SYSTEMIC LESIONS					
Multiple Organs	*(36)	*(35)	*(36)	*(35)	*(36)
Lymphoma Malignant					

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

\* Number of animals with any tissue examined microscopically

TDMS No. 20406 - 01  
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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
<b>Disposition Summary</b>					
Animals Initially in Study	35	36	36	36	36
Early Deaths					
Accidentally 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

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

\* Number of animals with any tissue examined microscopically

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_HI NO_SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
None					
<b>INTEGUMENTARY SYSTEM</b>					
Skin, Control	(35)	(36)	(36)	(35)	(36)
Squamous Cell Carcinoma, One					
Squamous Cell Papilloma, One		1 (3%)			
Subcutaneous Tissue, Mast Cell Tumor Malignant					
Skin, Site Of Application	(35)	(36)	(36)	(35)	(36)
Basal Cell Carcinoma, One					
Fibrosarcoma			1 (3%)		
Lymphoma Malignant		1 (3%)			
Squamous Cell Carcinoma, One			13 (36%)	9 (26%)	11 (31%)
Squamous Cell Carcinoma, Two			5 (14%)	4 (11%)	5 (14%)
Squamous Cell Carcinoma, Three			1 (3%)	2 (6%)	2 (6%)
Squamous Cell Carcinoma, Four					
Squamous Cell Carcinoma, Greater Than Five					
Squamous Cell Carcinoma In Situ, One		5 (14%)	11 (31%)	8 (23%)	6 (17%)
Squamous Cell Carcinoma In Situ, Two		1 (3%)	7 (19%)	6 (17%)	7 (19%)
Squamous Cell Carcinoma In Situ, Three			3 (8%)	5 (14%)	3 (8%)
Squamous Cell Carcinoma In Situ, Four			2 (6%)	1 (3%)	5 (14%)
Squamous Cell Carcinoma In Situ, Five			3 (8%)	1 (3%)	4 (11%)
Squamous Cell Carcinoma In Situ, Greater Than Five		1 (3%)	5 (14%)	5 (14%)	3 (8%)
Squamous Cell Papilloma, One		2 (6%)	14 (39%)	7 (20%)	7 (19%)
Squamous Cell Papilloma, Two		2 (6%)	5 (14%)	3 (9%)	4 (11%)
Squamous Cell Papilloma, Three			1 (3%)	3 (9%)	1 (3%)
Squamous Cell Papilloma, Four		1 (3%)	1 (3%)	1 (3%)	1 (3%)
Squamous Cell Papilloma, Five				1 (3%)	2 (6%)
Squamous Cell Papilloma, Greater Than Five			1 (3%)	1 (3%)	4 (11%)
Sebaceous Gland, Adenoma, One		1 (3%)			
<b>MUSCULOSKELETAL SYSTEM</b>					
None					

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

\* Number of animals with any tissue examined microscopically

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NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					
SYSTEMIC LESIONS					
Multiple Organs	*(35)	*(36)	*(36)	*(35)	*(36)
Lymphoma Malignant		1 (3%)			

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	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL
<b>Disposition Summary</b>					
Animals Initially in Study	36	36	36	36	36
Early Deaths					
Accidentally 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

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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					
<b>INTEGUMENTARY SYSTEM</b>					
Skin, Control	(36)	(36)	(36)	(36)	(36)
Squamous Cell Carcinoma, One				1 (3%)	
Squamous Cell Papilloma, One					1 (3%)
Subcutaneous Tissue, Mast Cell Tumor Malignant					
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)
Basal Cell Carcinoma, One					
Fibrosarcoma					
Lymphoma Malignant			1 (3%)		1 (3%)
Squamous Cell Carcinoma, One	15 (42%)	12 (33%)	9 (25%)	9 (25%)	18 (50%)
Squamous Cell Carcinoma, Two	4 (11%)	5 (14%)	5 (14%)	4 (11%)	1 (3%)
Squamous Cell Carcinoma, Three			1 (3%)	1 (3%)	1 (3%)
Squamous Cell Carcinoma, Four	1 (3%)				
Squamous Cell Carcinoma, Greater Than Five					
Squamous Cell Carcinoma In Situ, One	3 (8%)	10 (28%)	2 (6%)	5 (14%)	4 (11%)
Squamous Cell Carcinoma In Situ, Two	7 (19%)	7 (19%)	7 (19%)	3 (8%)	8 (22%)
Squamous Cell Carcinoma In Situ, Three	8 (22%)	4 (11%)	2 (6%)	4 (11%)	1 (3%)
Squamous Cell Carcinoma In Situ, Four	4 (11%)	2 (6%)	7 (19%)	4 (11%)	6 (17%)
Squamous Cell Carcinoma In Situ, Five	3 (8%)	1 (3%)	4 (11%)	5 (14%)	2 (6%)
Squamous Cell Carcinoma In Situ, Greater Than Five	4 (11%)	5 (14%)	6 (17%)	8 (22%)	5 (14%)
Squamous Cell Papilloma, One	10 (28%)	6 (17%)	6 (17%)	5 (14%)	4 (11%)
Squamous Cell Papilloma, Two	5 (14%)	7 (19%)	10 (28%)	7 (19%)	7 (19%)
Squamous Cell Papilloma, Three	5 (14%)	1 (3%)	2 (6%)	2 (6%)	5 (14%)
Squamous Cell Papilloma, Four	4 (11%)	1 (3%)	3 (8%)		2 (6%)
Squamous Cell Papilloma, Five		2 (6%)	1 (3%)	1 (3%)	1 (3%)
Squamous Cell Papilloma, Greater Than Five	1 (3%)	3 (8%)	5 (14%)	4 (11%)	1 (3%)
Sebaceous Gland, Adenoma, One					

**MUSCULOSKELETAL SYSTEM**

None

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

\* Number of animals with any tissue examined microscopically

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

	SKH-1 HAIRLESS MICE (NCTR) MICE MALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL
NERVOUS SYSTEM	None					
RESPIRATORY SYSTEM	None					
SPECIAL SENSES SYSTEM	None					
URINARY SYSTEM	None					
SYSTEMIC LESIONS						
Multiple Organs		*(36)	*(36)	*(36)	*(36)	*(36)
Lymphoma Malignant				1 (3%)		1 (3%)

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

\* Number of animals with any tissue examined microscopically

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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

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#### ALIMENTARY SYSTEM

None

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#### CARDIOVASCULAR SYSTEM

None

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#### ENDOCRINE SYSTEM

None

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#### GENERAL BODY SYSTEM

None

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#### GENITAL SYSTEM

None

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#### HEMATOPOIETIC SYSTEM

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

\* Number of animals with any tissue examined microscopically

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
None			
<b>INTEGUMENTARY SYSTEM</b>			
Skin, Control	(34)	(36)	(36)
Squamous Cell Carcinoma, One			
Squamous Cell Papilloma, One		1 (3%)	1 (3%)
Subcutaneous Tissue, Mast Cell Tumor Malignant			1 (3%)
Skin, Site Of Application	(35)	(36)	(36)
Basal Cell Carcinoma, One		1 (3%)	
Fibrosarcoma			
Lymphoma Malignant	1 (3%)		
Squamous Cell Carcinoma, One	16 (46%)	14 (39%)	10 (28%)
Squamous Cell Carcinoma, Two	4 (11%)	9 (25%)	10 (28%)
Squamous Cell Carcinoma, Three	1 (3%)		5 (14%)
Squamous Cell Carcinoma, Four			
Squamous Cell Carcinoma, Greater Than Five			1 (3%)
Squamous Cell Carcinoma In Situ, One	4 (11%)	5 (14%)	2 (6%)
Squamous Cell Carcinoma In Situ, Two	7 (20%)	8 (22%)	8 (22%)
Squamous Cell Carcinoma In Situ, Three	5 (14%)	6 (17%)	2 (6%)
Squamous Cell Carcinoma In Situ, Four	5 (14%)	7 (19%)	7 (19%)
Squamous Cell Carcinoma In Situ, Five	2 (6%)	2 (6%)	3 (8%)
Squamous Cell Carcinoma In Situ, Greater Than Five	1 (3%)	2 (6%)	5 (14%)
Squamous Cell Papilloma, One	13 (37%)	5 (14%)	5 (14%)
Squamous Cell Papilloma, Two	5 (14%)	4 (11%)	3 (8%)
Squamous Cell Papilloma, Three	4 (11%)	4 (11%)	2 (6%)
Squamous Cell Papilloma, Four	2 (6%)	3 (8%)	
Squamous Cell Papilloma, Five	1 (3%)		
Squamous Cell Papilloma, Greater Than Five	2 (6%)	3 (8%)	
Sebaceous Gland, Adenoma, One			

**MUSCULOSKELETAL SYSTEM**

None

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

\* Number of animals with any tissue examined microscopically

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Lab: NCTR

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SKH-1 HAIRLESS MICE (NCTR) MICE MALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
None			
SPECIAL SENSES SYSTEM			
None			
URINARY SYSTEM			
None			
SYSTEMIC LESIONS			
Multiple Organs	*(35)	*(36)	*(36)
Lymphoma Malignant	1 (3%)		

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

\* Number of animals with any tissue examined microscopically

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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
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### Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	1
Total Primary Neoplasms	1
Total Animals with Benign Neoplasms	1
Total Benign Neoplasms	1
Total Animals with Malignant Neoplasms	
Total Malignant Neoplasms	
Total Animals with Metastatic Neoplasms	
Total Metastatic Neoplasms	
Total Animals with Malignant Neoplasms Uncertain Primary Site	
Total Animals with Neoplasms Uncertain-Benign or Malignant	
Total Uncertain Neoplasms	

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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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
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	10	36	31	31
Total Primary Neoplasms	15	73	57	65
Total Animals with Benign Neoplasms	5	22	16	19
Total Benign Neoplasms	7	22	16	19
Total Animals with Malignant Neoplasms	8	36	30	31
Total Malignant Neoplasms	8	51	41	46
Total Animals with Metastatic Neoplasms				
Total Metastatic Neoplasms				
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant				
Total Uncertain Neoplasms				

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a - Number of animals examined microscopically at site and number of animals with lesion  
 b - Primary tumors: all tumors except metastatic tumors  
 \* Number of animals with any tissue examined microscopically

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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
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**Tumor Summary for Males**

<b>Total Animals with Primary Neoplasms (b)</b>	36	32	33	33	32
<b>Total Primary Neoplasms</b>	74	66	71	63	68
<b>Total Animals with Benign Neoplasms</b>	25	20	27	19	20
<b>Total Benign Neoplasms</b>	25	20	27	19	21
<b>Total Animals with Malignant Neoplasms</b>	34	32	33	31	30
<b>Total Malignant Neoplasms</b>	49	46	44	44	47
<b>Total Animals with Metastatic Neoplasms</b>					
<b>Total Metastatic Neoplasms</b>					
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>					
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>					
<b>Total Uncertain Neoplasms</b>					

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a - Number of animals examined microscopically at site and number of animals with lesion  
 b - Primary tumors: all tumors except metastatic tumors  
 \* Number of animals with any tissue examined microscopically



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Lab: NCTR

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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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### Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	31	33	33
Total Primary Neoplasms	73	74	65
Total Animals with Benign Neoplasms	27	19	11
Total Benign Neoplasms	27	20	11
Total Animals with Malignant Neoplasms	29	32	33
Total Malignant Neoplasms	46	54	54
Total Animals with Metastatic Neoplasms			
Total Metastatic Neoplasms			
Total Animals with Malignant Neoplasms Uncertain Primary Site			
Total Animals with Neoplasms Uncertain-Benign or Malignant			
Total Uncertain Neoplasms			

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\*\*\* END OF MALE \*\*\*

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

a - Number of animals examined microscopically at site and number of animals with lesion  
b - Primary tumors: all tumors except metastatic tumors