

TDMS No. 20406 - 02
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: 09/26/2006
Time Report Reqsted: 12:27:23
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

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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
Disposition Summary					
Animals Initially in Study	36	36	36	36	36
Early Deaths					
Moribund Sacrifice	5	7	2	2	3
Natural Death	1		2		
Survivors					
Moribund Sacrifice			2		1
Terminal Sacrifice	30	28	30	33	32
Harvest		1		1	
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 FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant					1 (3%)
Squamous Cell Carcinoma, One					
Squamous Cell Carcinoma In Situ, One					
Squamous Cell Papilloma, One					
Sebaceous Gland, Adenoma					
Subcutaneous Tissue, Lipoma		1 (3%)			
Subcutaneous Tissue, Lymphoma Malignant		1 (3%)			
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant		1 (3%)			1 (3%)
Squamous Cell Carcinoma, One					
Squamous Cell Carcinoma, Two					
Squamous Cell Carcinoma, Three					
Squamous Cell Carcinoma, Four					
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				1 (3%)	
Squamous Cell Papilloma, Two					
Squamous Cell Papilloma, Three					
Squamous Cell Papilloma, Four					
Squamous Cell Papilloma, Five					
Squamous Cell Papilloma, Greater Than Five					
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS 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 FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL
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 FEMALE	AEMOD_H NO_SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
Disposition Summary					
Animals Initially in Study	36	36	36	36	36
Early Deaths					
Moribund Sacrifice		1	1	1	4
Natural Death	1	1			
Survivors					
Moribund Sacrifice	2	3			
Terminal Sacrifice	33	24	1	2	
Harvest		7	34	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

* Number of animals with any tissue examined microscopically

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	AEMOD_ H NO_ SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant					
Squamous Cell Carcinoma, One		2 (6%)			2 (6%)
Squamous Cell Carcinoma In Situ, One			1 (3%)		
Squamous Cell Papilloma, One		6 (17%)	1 (3%)		
Sebaceous Gland, Adenoma					
Subcutaneous Tissue, Lipoma					
Subcutaneous Tissue, Lymphoma Malignant					
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant		1 (3%)			
Squamous Cell Carcinoma, One		2 (6%)	16 (44%)	20 (56%)	15 (42%)
Squamous Cell Carcinoma, Two			5 (14%)	4 (11%)	5 (14%)
Squamous Cell Carcinoma, Three			1 (3%)	1 (3%)	2 (6%)
Squamous Cell Carcinoma, Four			1 (3%)		
Squamous Cell Carcinoma In Situ, One		4 (11%)	10 (28%)	9 (25%)	5 (14%)
Squamous Cell Carcinoma In Situ, Two		2 (6%)	5 (14%)	7 (19%)	6 (17%)
Squamous Cell Carcinoma In Situ, Three		2 (6%)	7 (19%)	6 (17%)	5 (14%)
Squamous Cell Carcinoma In Situ, Four			2 (6%)	3 (8%)	8 (22%)
Squamous Cell Carcinoma In Situ, Five		1 (3%)	1 (3%)	3 (8%)	4 (11%)
Squamous Cell Carcinoma In Situ, Greater Than Five			3 (8%)	2 (6%)	4 (11%)
Squamous Cell Papilloma, One		6 (17%)	7 (19%)	5 (14%)	4 (11%)
Squamous Cell Papilloma, Two		4 (11%)	5 (14%)	6 (17%)	5 (14%)
Squamous Cell Papilloma, Three		6 (17%)	3 (8%)	3 (8%)	5 (14%)
Squamous Cell Papilloma, Four				5 (14%)	2 (6%)
Squamous Cell Papilloma, Five			3 (8%)	1 (3%)	3 (8%)
Squamous Cell Papilloma, Greater Than Five			2 (6%)	1 (3%)	6 (17%)
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS 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

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	AEMOD_H NO_ SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					
SYSTEMIC LESIONS					
Multiple Organs	*(36)	*(36)	*(36)	*(36)	*(36)
Lymphoma Malignant		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 FEMALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL
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Disposition Summary

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

* Number of animals with any tissue examined microscopically

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL
INTEGUMENTARY SYSTEM					
Skin, Control	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant					1 (3%)
Squamous Cell Carcinoma, One			1 (3%)		
Squamous Cell Carcinoma In Situ, One		1 (3%)	1 (3%)		
Squamous Cell Papilloma, One	1 (3%)	2 (6%)	1 (3%)	2 (6%)	2 (6%)
Sebaceous Gland, Adenoma					
Subcutaneous Tissue, Lipoma					
Subcutaneous Tissue, Lymphoma Malignant					
Skin, Site Of Application	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant		1 (3%)			1 (3%)
Squamous Cell Carcinoma, One	17 (47%)	16 (44%)	14 (39%)	10 (28%)	9 (25%)
Squamous Cell Carcinoma, Two	6 (17%)	2 (6%)	4 (11%)	4 (11%)	7 (19%)
Squamous Cell Carcinoma, Three		2 (6%)		1 (3%)	1 (3%)
Squamous Cell Carcinoma, Four					
Squamous Cell Carcinoma In Situ, One	7 (19%)	4 (11%)	6 (17%)	3 (8%)	7 (19%)
Squamous Cell Carcinoma In Situ, Two	6 (17%)	6 (17%)	10 (28%)	3 (8%)	4 (11%)
Squamous Cell Carcinoma In Situ, Three	3 (8%)	4 (11%)	4 (11%)	6 (17%)	2 (6%)
Squamous Cell Carcinoma In Situ, Four	2 (6%)	2 (6%)	4 (11%)	4 (11%)	6 (17%)
Squamous Cell Carcinoma In Situ, Five	5 (14%)	3 (8%)	1 (3%)	7 (19%)	5 (14%)
Squamous Cell Carcinoma In Situ, Greater Than Five	5 (14%)	12 (33%)	3 (8%)	9 (25%)	5 (14%)
Squamous Cell Papilloma, One	7 (19%)	5 (14%)	4 (11%)	7 (19%)	6 (17%)
Squamous Cell Papilloma, Two	4 (11%)	8 (22%)	6 (17%)	7 (19%)	7 (19%)
Squamous Cell Papilloma, Three	4 (11%)	5 (14%)	6 (17%)	6 (17%)	5 (14%)
Squamous Cell Papilloma, Four	8 (22%)	2 (6%)	4 (11%)	2 (6%)	3 (8%)
Squamous Cell Papilloma, Five	1 (3%)		3 (8%)	3 (8%)	
Squamous Cell Papilloma, Greater Than Five	5 (14%)	6 (17%)	6 (17%)	5 (14%)	10 (28%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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

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

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL
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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First Dose M/F: NA / 05/11/03
Lab: NCTR

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

Animals Initially in Study	36	36	36
Early Deaths			
Moribund Sacrifice	4	1	1
Natural Death		2	
Survivors			
Moribund Sacrifice			
Terminal Sacrifice			
Harvest	32	33	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

None

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 FEMALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
INTEGUMENTARY SYSTEM			
Skin, Control	(36)	(36)	(36)
Lymphoma Malignant			
Squamous Cell Carcinoma, One			
Squamous Cell Carcinoma In Situ, One			
Squamous Cell Papilloma, One	1 (3%)	1 (3%)	
Sebaceous Gland, Adenoma	1 (3%)		
Subcutaneous Tissue, Lipoma			
Subcutaneous Tissue, Lymphoma Malignant			
Skin, Site Of Application	(36)	(36)	(36)
Lymphoma Malignant			
Squamous Cell Carcinoma, One	19 (53%)	11 (31%)	8 (22%)
Squamous Cell Carcinoma, Two	1 (3%)	3 (8%)	7 (19%)
Squamous Cell Carcinoma, Three	2 (6%)	4 (11%)	1 (3%)
Squamous Cell Carcinoma, Four		1 (3%)	1 (3%)
Squamous Cell Carcinoma In Situ, One	9 (25%)	5 (14%)	7 (19%)
Squamous Cell Carcinoma In Situ, Two	4 (11%)	6 (17%)	4 (11%)
Squamous Cell Carcinoma In Situ, Three	3 (8%)	6 (17%)	7 (19%)
Squamous Cell Carcinoma In Situ, Four	5 (14%)	5 (14%)	3 (8%)
Squamous Cell Carcinoma In Situ, Five	2 (6%)	3 (8%)	1 (3%)
Squamous Cell Carcinoma In Situ, Greater Than Five	4 (11%)	6 (17%)	1 (3%)
Squamous Cell Papilloma, One	4 (11%)	7 (19%)	8 (22%)
Squamous Cell Papilloma, Two	4 (11%)	9 (25%)	3 (8%)
Squamous Cell Papilloma, Three	6 (17%)	4 (11%)	2 (6%)
Squamous Cell Papilloma, Four	3 (8%)	2 (6%)	
Squamous Cell Papilloma, Five	6 (17%)	2 (6%)	1 (3%)
Squamous Cell Papilloma, Greater Than Five	4 (11%)	5 (14%)	2 (6%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS 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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Pathologist: MELLICK, P.

Date Report Requested: 09/26/2006

Time Report Requested: 12:27:23

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

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
RESPIRATORY SYSTEM			
None			
SPECIAL SENSES SYSTEM			
None			
URINARY SYSTEM			
None			
SYSTEMIC LESIONS			
Multiple Organs	*(36)	*(36)	*(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

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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
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	2			1	1
Total Primary Neoplasms	2			1	1
Total Animals with Benign Neoplasms	1			1	
Total Benign Neoplasms	1			1	
Total Animals with Malignant Neoplasms	1				1
Total Malignant Neoplasms	1				1
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					

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

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SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	AEMOD_ H NO_ SSL	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	23	35	35	33
Total Primary Neoplasms	36	73	76	81
Total Animals with Benign Neoplasms	18	20	21	25
Total Benign Neoplasms	22	21	21	25
Total Animals with Malignant Neoplasms	13	34	35	33
Total Malignant Neoplasms	14	52	55	56
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				

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

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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	33	34	34	34	35
Total Primary Neoplasms	81	81	78	79	80
Total Animals with Benign Neoplasms	29	26	29	30	31
Total Benign Neoplasms	30	28	30	32	33
Total Animals with Malignant Neoplasms	32	33	32	33	33
Total Malignant Neoplasms	51	53	48	47	47
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					

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

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	34	33	32
Total Primary Neoplasms	78	80	56
Total Animals with Benign Neoplasms	27	29	16
Total Benign Neoplasms	29	30	16
Total Animals with Malignant Neoplasms	32	32	28
Total Malignant Neoplasms	49	50	40
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			

*** 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