

**Experiment Number:** 20406-02  
**Test Type:** 1-YEAR  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/SKH-1/NCTR

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS  
ABRIDGED) (a)**

**Test Compound:** Aloe phototoxicity studies  
**CAS Number:** ALOEPHOTOTOX

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 13:01:48  
**First Dose M/F:** NA / NA  
**Lab:** NCTR

**C Number:** C20406  
**Lock Date:** 12/02/2008  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Female  
**PWG Approval Date:** NONE

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**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)**  
 Test Compound: Aloe phototoxicity studies  
 CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014  
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 First Dose M/F: NA / NA  
 Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
<b>Disposition Summary</b>						
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

Skin, Control (36) (36) (36) (36) (36) (36)

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/NCTR Mouse FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
Sebacous GI, Adenoma						
Squamous Cell Carcinoma In Situ, One						
Squamous Cell Carcinoma, One						
Squamous Cell Papilloma, One						
Subcut Tiss, Lipoma		1 (3%)				
Skin, Site Of Application	(3)	(0)	(0)	(0)	(0)	(0)
Skin, Site of Application	(33)	(36)	(36)	(36)	(36)	(36)
Squamous Cell Carcinoma In Situ, > Five						
Squamous Cell Carcinoma In Situ, Five						
Squamous Cell Carcinoma In Situ, Four						
Squamous Cell Carcinoma In Situ, One						
Squamous Cell Carcinoma In Situ, Three						
Squamous Cell Carcinoma In Situ, Two						
Squamous Cell Carcinoma, Four						
Squamous Cell Carcinoma, One						
Squamous Cell Carcinoma, Three						
Squamous Cell Carcinoma, Two						
Squamous Cell Papilloma, > Five						
Squamous Cell Papilloma, Five						
Squamous Cell Papilloma, Four						
Squamous Cell Papilloma, One				1 (3%)		
Squamous Cell Papilloma, Three						
Squamous Cell Papilloma, Two						

**MUSCULOSKELETAL SYSTEM**  
 None

**NERVOUS SYSTEM**  
 None

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

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM None						
SYSTEMIC LESIONS						
Multiple Organ	*(36)	*(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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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 Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
<b>Disposition Summary</b>						
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						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Sebaceous G, Adenoma						

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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CAS Number: ALOEPHOTOTOX

First Dose M/F: NA / NA

Species/Strain: Mouse/SKH-1/NCTR

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
Squamous Cell Carcinoma In Situ, One		1 (3%)				1 (3%)
Squamous Cell Carcinoma, One	2 (6%)			2 (6%)		
Squamous Cell Papilloma, One	6 (17%)	1 (3%)			1 (3%)	2 (6%)
Subcut Tiss, Lipoma						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(0)	(1)
Skin, Site of Application	(36)	(36)	(36)	(36)	(36)	(35)
Squamous Cell Carcinoma In Situ, > Five		3 (8%)	2 (6%)	4 (11%)	5 (14%)	12 (34%)
Squamous Cell Carcinoma In Situ, Five	1 (3%)	1 (3%)	3 (8%)	4 (11%)	5 (14%)	3 (9%)
Squamous Cell Carcinoma In Situ, Four		2 (6%)	3 (8%)	8 (22%)	2 (6%)	2 (6%)
Squamous Cell Carcinoma In Situ, One	4 (11%)	10 (28%)	9 (25%)	5 (14%)	7 (19%)	4 (11%)
Squamous Cell Carcinoma In Situ, Three	2 (6%)	7 (19%)	6 (17%)	5 (14%)	3 (8%)	4 (11%)
Squamous Cell Carcinoma In Situ, Two	2 (6%)	5 (14%)	7 (19%)	6 (17%)	6 (17%)	6 (17%)
Squamous Cell Carcinoma, Four		1 (3%)				
Squamous Cell Carcinoma, One	2 (6%)	16 (44%)	20 (56%)	15 (42%)	17 (47%)	16 (46%)
Squamous Cell Carcinoma, Three		1 (3%)	1 (3%)	2 (6%)		2 (6%)
Squamous Cell Carcinoma, Two		5 (14%)	4 (11%)	5 (14%)	6 (17%)	2 (6%)
Squamous Cell Papilloma, > Five		2 (6%)	1 (3%)	6 (17%)	5 (14%)	6 (17%)
Squamous Cell Papilloma, Five		3 (8%)	1 (3%)	3 (8%)	1 (3%)	
Squamous Cell Papilloma, Four			5 (14%)	2 (6%)	8 (22%)	2 (6%)
Squamous Cell Papilloma, One	6 (17%)	7 (19%)	5 (14%)	4 (11%)	7 (19%)	5 (14%)
Squamous Cell Papilloma, Three	6 (17%)	3 (8%)	3 (8%)	5 (14%)	4 (11%)	5 (14%)
Squamous Cell Papilloma, Two	4 (11%)	5 (14%)	6 (17%)	5 (14%)	4 (11%)	8 (23%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						
SYSTEMIC LESIONS						
Multiple Organ	*(36)	*(36)	*(36)	*(36)	*(36)	*(36)
Lymphoma Malignant	1 (3%)					1 (3%)

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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/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
<b>Disposition Summary</b>						
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						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Sebaceous GI, Adenoma				1 (3%)		

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

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CAS Number: ALOEPHOTOTOX

First Dose M/F: NA / NA

Species/Strain: Mouse/SKH-1/NCTR

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
Squamous Cell Carcinoma In Situ, One	1 (3%)					
Squamous Cell Carcinoma, One	1 (3%)					
Squamous Cell Papilloma, One	1 (3%)	2 (6%)	2 (6%)	1 (3%)	1 (3%)	
Subcut Tiss, Lipoma						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(1)	(0)
Skin, Site of Application	(36)	(36)	(36)	(36)	(35)	(36)
Squamous Cell Carcinoma In Situ, > Five	3 (8%)	9 (25%)	5 (14%)	4 (11%)	6 (17%)	1 (3%)
Squamous Cell Carcinoma In Situ, Five	1 (3%)	7 (19%)	5 (14%)	2 (6%)	3 (9%)	1 (3%)
Squamous Cell Carcinoma In Situ, Four	4 (11%)	4 (11%)	6 (17%)	5 (14%)	5 (14%)	3 (8%)
Squamous Cell Carcinoma In Situ, One	6 (17%)	3 (8%)	7 (19%)	9 (25%)	5 (14%)	7 (19%)
Squamous Cell Carcinoma In Situ, Three	4 (11%)	6 (17%)	2 (6%)	3 (8%)	6 (17%)	7 (19%)
Squamous Cell Carcinoma In Situ, Two	10 (28%)	3 (8%)	4 (11%)	4 (11%)	6 (17%)	4 (11%)
Squamous Cell Carcinoma, Four					1 (3%)	1 (3%)
Squamous Cell Carcinoma, One	14 (39%)	10 (28%)	9 (25%)	19 (53%)	11 (31%)	8 (22%)
Squamous Cell Carcinoma, Three		1 (3%)	1 (3%)	2 (6%)	4 (11%)	1 (3%)
Squamous Cell Carcinoma, Two	4 (11%)	4 (11%)	7 (19%)	1 (3%)	3 (9%)	7 (19%)
Squamous Cell Papilloma, > Five	6 (17%)	5 (14%)	10 (28%)	4 (11%)	5 (14%)	2 (6%)
Squamous Cell Papilloma, Five	3 (8%)	3 (8%)		6 (17%)	2 (6%)	1 (3%)
Squamous Cell Papilloma, Four	4 (11%)	2 (6%)	3 (8%)	3 (8%)	2 (6%)	
Squamous Cell Papilloma, One	4 (11%)	7 (19%)	6 (17%)	4 (11%)	7 (20%)	8 (22%)
Squamous Cell Papilloma, Three	6 (17%)	6 (17%)	5 (14%)	6 (17%)	4 (11%)	2 (6%)
Squamous Cell Papilloma, Two	6 (17%)	7 (19%)	7 (19%)	4 (11%)	9 (26%)	3 (8%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						
SYSTEMIC LESIONS						
Multiple Organ	*(36)	*(36)	*(36)	*(36)	*(36)	*(36)
Lymphoma Malignant			1 (3%)			

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

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SKH-1/NCTR Mouse FEMALE	NOCREAM NO_ SSL	VEHICLE NO_ SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
<b>Tumor Summary for FEMALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>		2		1		1
<b>Total Primary Neoplasms</b>		2		1		1
<b>Total Animals with Benign Neoplasms</b>		1		1		
<b>Total Benign Neoplasms</b>		1		1		
<b>Total Animals with Malignant Neoplasms</b>		1				1
<b>Total Malignant Neoplasms</b>		1				1
<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>						

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

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\* Number of animals with any tissue examined microscopically

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 Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
<b>Tumor Summary for FEMALE</b>						
Total Animals with Primary Neoplasms (b)	23	35	35	33	33	34
Total Primary Neoplasms	36	73	76	81	81	81
Total Animals with Benign Neoplasms	18	20	21	25	29	26
Total Benign Neoplasms	22	21	21	25	30	28
Total Animals with Malignant Neoplasms	13	34	35	33	32	33
Total Malignant Neoplasms	14	52	55	56	51	53
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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SKH-1/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
<b>Tumor Summary for FEMALE</b>						
Total Animals with Primary Neoplasms (b)	34	34	35	34	33	32
Total Primary Neoplasms	78	79	80	78	80	56
Total Animals with Benign Neoplasms	29	30	31	27	29	16
Total Benign Neoplasms	30	32	33	29	30	16
Total Animals with Malignant Neoplasms	32	33	33	32	32	28
Total Malignant Neoplasms	48	47	47	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

\* Number of animals with any tissue examined microscopically