

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

**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**

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

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 13:01:39  
**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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**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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**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**  
**Test Compound:** Aloe phototoxicity studies  
**CAS Number:** ALOEPHOTOTOX

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 13:01:40  
**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
Lymphoma Malignant					1 (3%)	
Sebaceous GI, Adenoma						
Squamous Cell Carcinoma In Situ, One						
Squamous Cell Carcinoma, One						
Squamous Cell Papilloma, One						
Subcut Tiss, Lipoma		1 (3%)				
Subcut Tiss, Lymphoma Malignant		1 (3%)				
Skin, Site Of Application	(3)	(0)	(0)	(0)	(0)	(0)
Skin, Site of Application	(33)	(36)	(36)	(36)	(36)	(36)
Lymphoma Malignant		1 (3%)			1 (3%)	
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

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
None						
NERVOUS SYSTEM						
None						
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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 First Dose M/F: NA / NA  
 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
<b>Early Deaths</b>						
Moribund Sacrifice	1	1	1	4	4	2
Natural Death	1				1	1
<b>Survivors</b>						
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)
Lymphoma Malignant						

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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Time Report Requested: 13:01:40

Route: SKIN APPLICATION

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
Sebacous GI, Adenoma						
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						
Subcut Tiss, Lymphoma Malignant						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(0)	(1)
Skin, Site of Application	(36)	(36)	(36)	(36)	(36)	(35)
Lymphoma Malignant	1 (3%)					1 (3%)
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

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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**First Dose M/F:** NA / NA  
**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
NERVOUS SYSTEM						
None						
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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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>						
<b>Animals Initially In Study</b>	36	36	36	36	36	36
<b>Early Deaths</b>						
<b>Moribund Sacrifice</b>	1		2	4	1	1
<b>Natural Death</b>	3	2	1		2	
<b>Survivors</b>						
<b>Moribund Sacrifice</b>						
<b>Terminal Sacrifice</b>						
<b>Harvest</b>	32	34	33	32	33	35
<b>Animals Examined Microscopically</b>	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)
Lymphoma Malignant			1 (3%)			

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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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
Sebaceous GI, Adenoma				1 (3%)		
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						
Subcut Tiss, Lymphoma Malignant						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(1)	(0)
Skin, Site of Application	(36)	(36)	(36)	(36)	(35)	(36)
Lymphoma Malignant			1 (3%)			
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

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	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	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 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

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
<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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**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>						
<b>Total Animals with Primary Neoplasms (b)</b>	23	35	35	33	33	34
<b>Total Primary Neoplasms</b>	36	73	76	81	81	81
<b>Total Animals with Benign Neoplasms</b>	18	20	21	25	29	26
<b>Total Benign Neoplasms</b>	22	21	21	25	30	28
<b>Total Animals with Malignant Neoplasms</b>	13	34	35	33	32	33
<b>Total Malignant Neoplasms</b>	14	52	55	56	51	53
<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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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>						
<b>Total Animals with Primary Neoplasms (b)</b>	<b>34</b>	<b>34</b>	<b>35</b>	<b>34</b>	<b>33</b>	<b>32</b>
<b>Total Primary Neoplasms</b>	<b>78</b>	<b>79</b>	<b>80</b>	<b>78</b>	<b>80</b>	<b>56</b>
<b>Total Animals with Benign Neoplasms</b>	<b>29</b>	<b>30</b>	<b>31</b>	<b>27</b>	<b>29</b>	<b>16</b>
<b>Total Benign Neoplasms</b>	<b>30</b>	<b>32</b>	<b>33</b>	<b>29</b>	<b>30</b>	<b>16</b>
<b>Total Animals with Malignant Neoplasms</b>	<b>32</b>	<b>33</b>	<b>33</b>	<b>32</b>	<b>32</b>	<b>28</b>
<b>Total Malignant Neoplasms</b>	<b>48</b>	<b>47</b>	<b>47</b>	<b>49</b>	<b>50</b>	<b>40</b>
<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>						

**\*\* 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