Species/Strain: Mouse/SKH-1/NCTR

Test Type: 1-YEAR

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/23/2014 AVERAGE SEVERITY GRADES[b]

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Time Report Requested: 13:00:07

First Dose M/F: NA / NA

Lab: NCTR

C Number: C20406

Lock Date: 12/02/2008

ΑII **Cage Range:**

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Female

PWG Approval Date NONE

Route: SKIN APPLICATION

Test Type: 1-YEAR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:07

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX Lab: NCTR

Time Report Requested: 13:00:07

First Dose M/F: NA / NA

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
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						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess	(00)	2 [2.5]	1 [4.0]	(00)	(00)	1 [4.0]
		_ [2.0]	. [•]			. [•]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Route: SKIN APPLICATION

Test Type: 1-YEAR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:08

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

Lab: NCTR

Time Report Requested: 13:00:08

First Dose M/F: NA / NA

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
Cyst Epithelial Inclusion	3	6	3	3	4	1
Dermis, Inflammation, Chronic Active	32 [1.5]	32 [1.6]	35 [1.5]	36 [1.8]	34 [1.4]	36 [1.7]
Dermis, Inflammation, Granulomatous						
Edema		1 [3.0]			1 [3.0]	
Epidermis, Necrosis						
Hemorrhage		1 [3.0]				
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squamous	1 [1.0]	5 [1.2]	1 [1.0]	4 [1.3]		
Inflammation, Pyogranulomat		1 [4.0]		1 [3.0]		2 [3.0]
Subcut Tiss, Abscess						1 [4.0]
Subcut Tiss, Inflammation, Chronic						
Skin, Site Of Application	(3)	(0)	(0)	(0)	(0)	(0)
Skin, Site of Application	(33)	(36)	(36)	(36)	(36)	(36)
Abscess		1 [3.0]				
Cyst						
Cyst Epithelial Inclusion	3		2	2	5	6
Dermis, Inflammation, Chronic Active	33 [1.5]	36 [1.9]	36 [1.8]	36 [1.8]	36 [1.7]	36 [1.9]
Edema					1 [3.0]	
Epidermis, Necrosis						
Granuloma		1				
Hyperplasia, Squam Atypical, Focal, > Five						
Hyperplasia, Squam Atypical, Focal, Five						
Hyperplasia, Squam Atypical, Focal, Four						
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squam Atypical, Focal, Three						
Hyperplasia, Squam Atypical, Focal, Two						
Hyperplasia, Squamous Inflammation, Pyogranulomat	1 [1.0]	10 [1.2]	13 [1.0]	2 [1.0]	1 [1.0]	2 [1.5]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/SKH-1/NCTR

Test Type: 1-YEAR

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014
Time Report Requested: 13:00:08

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

First Dose M/F: NA / NA

Time Report Requested: 13:00:08

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
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM None						

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/SKH-1/NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:08

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Time Report Requested: 13:00:08 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% 13.7S
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						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess					3 [4.0]	
Cyst Epithelial Inclusion	7	3	3	5	5	4

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/SKH-1/NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:08

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

Time Report Requested: 13:00:08

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
Dermis, Inflammation, Chronic Active	35 [1.4]	29 [1.4]	29 [1.1]	30 [1.2]	35 [1.1]	32 [1.3]
Dermis, Inflammation, Granulomatous						
Edema						
Epidermis, Necrosis		1 [4.0]		2 [2.5]		
Hemorrhage		1 [3.0]				
Hyperplasia, Squam Atypical, Focal, One			1	1	1	1
Hyperplasia, Squamous	1 [1.0]	12 [1.2]	3 [1.3]			
Inflammation, Pyogranulomat		1 [4.0]		3 [3.3]		
Subcut Tiss, Abscess			1 [4.0]			
Subcut Tiss, Inflammation, Chronic		1 [3.0]				
Skin, Site Of Application	(0)	(0)	(0)	(0)	(0)	(1)
Skin, Site of Application	(36)	(36)	(36)	(36)	(36)	(35)
Abscess						
Cyst			1 [3.0]			
Cyst Epithelial Inclusion	6	5	5	10	5	8
Dermis, Inflammation, Chronic Active	36 [1.9]	36 [2.1]	36 [2.0]	36 [1.9]	36 [1.9]	35 [2.0]
Edema						
Epidermis, Necrosis			1 [3.0]	3 [3.0]		1 [3.0]
Granuloma			1		1	
Hyperplasia, Squam Atypical, Focal, > Five	1	5	5	2	2	2
Hyperplasia, Squam Atypical, Focal, Five	1	1	4	1	4	6
Hyperplasia, Squam Atypical, Focal, Four		3	7	3	3	4
Hyperplasia, Squam Atypical, Focal, One	10	7	8	10	10	6
Hyperplasia, Squam Atypical, Focal, Three	1	8	7	3	5	5
Hyperplasia, Squam Atypical, Focal, Two	2	8	4	8	5	10
Hyperplasia, Squamous	32 [1.3]	36 [1.8]	35 [2.1]	34 [2.0]	33 [2.1]	35 [1.8]
Inflammation, Pyogranulomat		2 [2.5]	1 [3.0]			2 [2.0]

MUSCULOSKELETAL SYSTEM

None

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: 1-YEAR

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014
Time Report Requested: 13:00:08

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

First Dose M/F: NA / NA

Time Report Requested: 13:00:08

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						

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: 1-YEAR

Route: SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:08

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

Lab: NCTR

Time Report Requested: 13:00:08

First Dose M/F: NA / NA

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
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						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess				1 [4.0]		
Cyst Epithelial Inclusion	3	5	2	3	1	1

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/SKH-1/NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 13:00:08

Test Compound: Aloe phototoxicity studies

First Dose M/F: NA / NA Lab: NCTR

Time Report Requested: 13:00:08

CAS Number: ALOEPHOTOTOX

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
Dermis, Inflammation, Chronic Active	30 [1.2]	33 [1.2]	29 [1.2]	31 [1.4]	30 [1.3]	19 [1.3]
Dermis, Inflammation, Granulomatous	1 [2.0]					
Edema						
Epidermis, Necrosis		1 [4.0]				
Hemorrhage	1 [2.0]					
Hyperplasia, Squam Atypical, Focal, One			1	1	1	
Hyperplasia, Squamous	1 [2.0]		4 [1.5]			
Inflammation, Pyogranulomat		1 [4.0]	1 [4.0]		1 [3.0]	
Subcut Tiss, Abscess						
Subcut Tiss, Inflammation, Chronic						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(1)	(0)
Skin, Site of Application	(36)	(36)	(36)	(36)	(35)	(36)
Abscess						
Cyst						
Cyst Epithelial Inclusion	1	7	5	5		2
Dermis, Inflammation, Chronic Active	33 [1.9]	35 [2.0]	33 [1.9]	35 [1.9]	35 [1.9]	32 [1.8]
Edema						
Epidermis, Necrosis		4 [3.3]	3 [4.0]	1 [4.0]	1 [4.0]	3 [3.3]
Granuloma	2					
Hyperplasia, Squam Atypical, Focal, > Five	2	1	7	2	2	7
Hyperplasia, Squam Atypical, Focal, Five	3		1	3	4	4
Hyperplasia, Squam Atypical, Focal, Four	6	1	4	6	5	7
Hyperplasia, Squam Atypical, Focal, One	5	12	6	8	6	5
Hyperplasia, Squam Atypical, Focal, Three	6	9	3	8	5	5
Hyperplasia, Squam Atypical, Focal, Two	7	9	6	5	5	6
Hyperplasia, Squamous	32 [2.0]	34 [2.0]	35 [1.9]	34 [1.9]	34 [1.8]	34 [1.9]
Inflammation, Pyogranulomat			2 [3.5]	1 [4.0]		

MUSCULOSKELETAL SYSTEM

None

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/SKH-1/NCTR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/23/2014

AVERAGE SEVERITY GRADES[b]

Time Report Requested: 13:00:08

First Dose M/F: NA / NA

Lab: NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

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

WHLEAF6% 13.7SSL CHARL3% 13.7SSL CHARCL6% 13.7SSL AEMOD_LO 13.7SSL AEMOD_HI 13.7SSL NOCREAM 20.5SSL SKH-1/NCTR Mouse FEMALE **NERVOUS SYSTEM** None RESPIRATORY SYSTEM None SPECIAL SENSES SYSTEM None **URINARY SYSTEM** None

** END OF REPORT **

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)