

Experiment Number: 20406-01
Test Type: 1-YEAR
Route: SKIN APPLICATION
Species/Strain: Mouse/SKH-1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014

Time Report Requested: 13:12:12

First Dose M/F: NA / 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: All
Study Gender: Male
PWG Approval Date: NONE

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| SKH-1/NCTR Mouse MALE | NOCREAM NO_SSL | VEHICLE NO_SSL | ALOGEL6% NO_SSL | WHLEAF6% NO_SSL | CHARCL6% NO_SSL | AEMOD_HI NO_SSL |
|----------------------------------|----------------|----------------|-----------------|-----------------|-----------------|-----------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 36 | 35 | 36 | 36 | 36 | 35 |
| Early Deaths | | | | | | |
| Accidentally Killed | | | 1 | | | |
| Moribund Sacrifice | | 5 | 1 | 4 | 3 | 7 |
| Natural Death | 1 | | | 1 | 2 | |
| Survivors | | | | | | |
| Moribund Sacrifice | | | | | | |
| Natural Death | | | | 1 | | |
| Terminal Sacrifice | 35 | 30 | 34 | 30 | 30 | 27 |
| Harvest | | | | | 1 | 1 |
| Animals Examined Microscopically | 36 | 35 | 36 | 35 | 36 | 35 |
| ALIMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| None | | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| None | | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| None | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| Skin, Control | (36) | (35) | (36) | (35) | (36) | (35) |

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

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Lab: NCTR

| SKH-1/NCTR Mouse MALE | NOCREAM NO_SSL | VEHICLE NO_SSL | ALOGEL6% NO_SSL | WHLEAF6% NO_SSL | CHARCL6% NO_SSL | AEMOD_HI NO_SSL |
|--|----------------|----------------|-----------------|-----------------|-----------------|-----------------|
| Abscess | | | | | | |
| Cyst Epithelial Inclusion | 2 (6%) | 3 (9%) | 1 (3%) | 3 (9%) | 4 (11%) | 3 (9%) |
| Dermis, Inflammation, Chronic Active | 34 (94%) | 31 (89%) | 34 (94%) | 32 (91%) | 36 (100%) | 32 (91%) |
| Developmental Malformation | | | | | | |
| Epidermis, Necrosis | 2 (6%) | | 1 (3%) | 1 (3%) | 1 (3%) | |
| Granuloma | | | | | | |
| Hyperplasia, Squam Atypical, Focal, One | | | | | | |
| Hyperplasia, Squamous | 2 (6%) | 2 (6%) | 2 (6%) | 1 (3%) | 1 (3%) | |
| Inflammation, Pyogranulomat | 3 (8%) | | 3 (8%) | 3 (9%) | 3 (8%) | |
| Subcut Tiss, Edema | | | | | | |
| Skin, Site Of Application | (0) | (2) | (0) | (1) | (0) | (2) |
| Skin, Site of Application | (36) | (33) | (36) | (34) | (36) | (33) |
| Abscess | | | | | | |
| Cyst Epithelial Inclusion | 1 (3%) | 2 (6%) | 4 (11%) | 3 (9%) | 5 (14%) | 9 (27%) |
| Dermis, Inflammation, Chronic Active | 36 (100%) | 33 (100%) | 36 (100%) | 34 (100%) | 36 (100%) | 33 (100%) |
| Epidermis, Necrosis | | 1 (3%) | | | 1 (3%) | |
| Granuloma | | | | 1 (3%) | | |
| Hyperplasia, Squam Atypical, Focal, > Five | | | | | | |
| Hyperplasia, Squam Atypical, Focal, Five | | | | | | |
| Hyperplasia, Squam Atypical, Focal, Four | | | | | | |
| Hyperplasia, Squam Atypical, Focal, One | | | | | | 1 (3%) |
| Hyperplasia, Squam Atypical, Focal, Three | | | | | | |
| Hyperplasia, Squam Atypical, Focal, Two | | | | | | |
| Hyperplasia, Squamous | 1 (3%) | 1 (3%) | 1 (3%) | | 1 (3%) | 1 (3%) |
| Inflammation, Pyogranulomat | | | | | 1 (3%) | |
| Subcut Tiss, Inflammation, Pyogranulomat | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |

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

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

| SKH-1/NCTR Mouse MALE | NOCREAM NO_SSL | VEHICLE NO_SSL | ALOGEL6% NO_SSL | WHLEAF6% NO_SSL | CHARCL6% NO_SSL | AEMOD_HI NO_SSL |
|-----------------------|----------------|----------------|-----------------|-----------------|-----------------|-----------------|
| 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

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

| SKH-1/NCTR Mouse MALE | NOCREAM 6.85SSL | NOCREAM 13.7SSL | VEHICLE 13.7SSL | ALOGEL3% 13.7SSL | ALOGEL6% 13.7SSL | WHLEAF3% 13.7SSL |
|----------------------------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|
| Disposition Summary | | | | | | |
| Animals Initially In Study | 36 | 36 | 35 | 36 | 36 | 36 |
| Early Deaths | | | | | | |
| Accidentally Killed | 1 | | | | | |
| Moribund Sacrifice | 5 | | 3 | 5 | 1 | 1 |
| Natural Death | 2 | | 1 | | | 2 |
| Survivors | | | | | | |
| Moribund Sacrifice | 1 | | | | | |
| Natural Death | | | | | | |
| Terminal Sacrifice | 22 | | | | | 1 |
| Harvest | 5 | 36 | 31 | 31 | 35 | 32 |
| Animals Examined Microscopically | 36 | 36 | 35 | 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) | (35) | (36) | (36) | (36) |

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 MALE | NOCREAM 6.85SSL | NOCREAM 13.7SSL | VEHICLE 13.7SSL | ALOGEL3% 13.7SSL | ALOGEL6% 13.7SSL | WHLEAF3% 13.7SSL |
|--|-----------------|-----------------|-----------------|------------------|------------------|------------------|
| Abscess | 2 (6%) | 1 (3%) | | 1 (3%) | | 1 (3%) |
| Cyst Epithelial Inclusion | 4 (11%) | 4 (11%) | 4 (11%) | 3 (8%) | 3 (8%) | |
| Dermis, Inflammation, Chronic Active | 30 (83%) | 22 (61%) | 30 (86%) | 26 (72%) | 30 (83%) | 31 (86%) |
| Developmental Malformation | | | | 1 (3%) | | |
| Epidermis, Necrosis | | 1 (3%) | 1 (3%) | 3 (8%) | 1 (3%) | |
| Granuloma | | | | | 2 (6%) | |
| Hyperplasia, Squam Atypical, Focal, One | | | | | 1 (3%) | |
| Hyperplasia, Squamous | | 2 (6%) | 2 (6%) | | 2 (6%) | 3 (8%) |
| Inflammation, Pyogranulomat | | 4 (11%) | | 2 (6%) | | 3 (8%) |
| Subcut Tiss, Edema | 1 (3%) | | | | | |
| Skin, Site Of Application | (2) | (0) | (0) | (2) | (0) | (0) |
| Skin, Site of Application | (34) | (36) | (35) | (34) | (36) | (36) |
| Abscess | 1 (3%) | | | | | |
| Cyst Epithelial Inclusion | 12 (35%) | 5 (14%) | 3 (9%) | 7 (21%) | 4 (11%) | 6 (17%) |
| Dermis, Inflammation, Chronic Active | 33 (97%) | 34 (94%) | 32 (91%) | 32 (94%) | 34 (94%) | 32 (89%) |
| Epidermis, Necrosis | | | | 2 (6%) | 3 (8%) | 2 (6%) |
| Granuloma | | | | | | |
| Hyperplasia, Squam Atypical, Focal, > Five | | 8 (22%) | 4 (11%) | 4 (12%) | 5 (14%) | 5 (14%) |
| Hyperplasia, Squam Atypical, Focal, Five | 1 (3%) | 2 (6%) | 5 (14%) | 3 (9%) | 5 (14%) | 4 (11%) |
| Hyperplasia, Squam Atypical, Focal, Four | 1 (3%) | 3 (8%) | 4 (11%) | 4 (12%) | 4 (11%) | 7 (19%) |
| Hyperplasia, Squam Atypical, Focal, One | 6 (18%) | 5 (14%) | 5 (14%) | 2 (6%) | 4 (11%) | 4 (11%) |
| Hyperplasia, Squam Atypical, Focal, Three | 1 (3%) | 6 (17%) | 7 (20%) | 5 (15%) | 6 (17%) | 4 (11%) |
| Hyperplasia, Squam Atypical, Focal, Two | 3 (9%) | 9 (25%) | 6 (17%) | 10 (29%) | 10 (28%) | 5 (14%) |
| Hyperplasia, Squamous | 20 (59%) | 35 (97%) | 31 (89%) | 33 (97%) | 36 (100%) | 34 (94%) |
| Inflammation, Pyogranulomat | 1 (3%) | 2 (6%) | | | 1 (3%) | 1 (3%) |
| Subcut Tiss, Inflammation, Pyogranulomat | | 1 (3%) | | | | |

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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

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Lab: NCTR

| SKH-1/NCTR Mouse MALE | NOCREAM 6.85SSL | NOCREAM 13.7SSL | VEHICLE 13.7SSL | ALOGEL3% 13.7SSL | ALOGEL6% 13.7SSL | WHLEAF3% 13.7SSL |
|------------------------------|------------------------|------------------------|------------------------|-------------------------|-------------------------|-------------------------|
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| None | | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| None | | | | | | |

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

| SKH-1/NCTR Mouse MALE | WHLEAF6% 13.7SSL | CHARCL3% 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 | 35 | 36 | 36 |
| Early Deaths | | | | | | |
| Accidentally Killed | | | | | | |
| Moribund Sacrifice | 2 | 2 | 4 | 3 | | 3 |
| Natural Death | 1 | 1 | | 2 | 1 | |
| Survivors | | | | | | |
| Moribund Sacrifice | | | | | | |
| Natural Death | | | | | | |
| Terminal Sacrifice | 1 | | | | 1 | |
| Harvest | 32 | 33 | 32 | 30 | 34 | 33 |
| Animals Examined Microscopically | 36 | 36 | 36 | 35 | 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) | (34) | (36) | (36) |

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

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Species/Strain: Mouse/SKH-1/NCTR

Lab: NCTR

| SKH-1/NCTR Mouse MALE | WHLEAF6% 13.7SSL | CHARCL3% 13.7SSL | CHARCL6% 13.7SSL | AEMOD_LO 13.7SSL | AEMOD_HI 13.7SSL | NOCREAM 20.5SSL |
|--|------------------|------------------|------------------|------------------|------------------|-----------------|
| Abscess | | | 1 (3%) | | 1 (3%) | 1 (3%) |
| Cyst Epithelial Inclusion | 3 (8%) | 2 (6%) | 4 (11%) | 2 (6%) | 6 (17%) | 1 (3%) |
| Dermis, Inflammation, Chronic Active | 30 (83%) | 27 (75%) | 33 (92%) | 28 (82%) | 34 (94%) | 20 (56%) |
| Developmental Malformation | | | | | | |
| Epidermis, Necrosis | 4 (11%) | 2 (6%) | | 5 (15%) | 1 (3%) | 1 (3%) |
| Granuloma | | | 1 (3%) | | | |
| Hyperplasia, Squam Atypical, Focal, One | | | | | | |
| Hyperplasia, Squamous | | 1 (3%) | 1 (3%) | 1 (3%) | 1 (3%) | |
| Inflammation, Pyogranulomat | 3 (8%) | | 1 (3%) | 4 (12%) | 2 (6%) | 1 (3%) |
| Subcut Tiss, Edema | | | | | | |
| Skin, Site Of Application | (1) | (0) | (1) | (0) | (1) | (0) |
| Skin, Site of Application | (35) | (36) | (35) | (35) | (35) | (36) |
| Abscess | 1 (3%) | | | | | 1 (3%) |
| Cyst Epithelial Inclusion | 2 (6%) | 5 (14%) | 4 (11%) | 3 (9%) | 2 (6%) | 1 (3%) |
| Dermis, Inflammation, Chronic Active | 33 (94%) | 34 (94%) | 34 (97%) | 35 (100%) | 32 (91%) | 26 (72%) |
| Epidermis, Necrosis | 2 (6%) | 6 (17%) | 5 (14%) | 7 (20%) | 1 (3%) | 5 (14%) |
| Granuloma | 1 (3%) | | | | | |
| Hyperplasia, Squam Atypical, Focal, > Five | 8 (23%) | 4 (11%) | 5 (14%) | 4 (11%) | 7 (20%) | 5 (14%) |
| Hyperplasia, Squam Atypical, Focal, Five | 1 (3%) | 3 (8%) | 4 (11%) | 3 (9%) | 5 (14%) | 2 (6%) |
| Hyperplasia, Squam Atypical, Focal, Four | 4 (11%) | | 10 (29%) | 8 (23%) | 4 (11%) | 6 (17%) |
| Hyperplasia, Squam Atypical, Focal, One | 4 (11%) | 4 (11%) | 5 (14%) | 5 (14%) | 8 (23%) | 7 (19%) |
| Hyperplasia, Squam Atypical, Focal, Three | 12 (34%) | 9 (25%) | 4 (11%) | 5 (14%) | 4 (11%) | 3 (8%) |
| Hyperplasia, Squam Atypical, Focal, Two | 5 (14%) | 14 (39%) | 2 (6%) | 5 (14%) | 5 (14%) | 9 (25%) |
| Hyperplasia, Squamous | 34 (97%) | 35 (97%) | 35 (100%) | 32 (91%) | 32 (91%) | 28 (78%) |
| Inflammation, Pyogranulomat | | | | 2 (6%) | | |
| Subcut Tiss, Inflammation, Pyogranulomat | | | | | | |

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

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

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SKH-1/NCTR Mouse MALE

WHLEAF6% 13.7SSL CHARCL3% 13.7SSL CHARCL6% 13.7SSL AEMOD_LO 13.7SSL AEMOD_HI 13.7SSL NOCREAM 20.5SSL

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

**** END OF REPORT ****