

**SCIENTIFIC STUDY OF COATS®
(COLLOIDAL OATMEAL SYSTEM)
COATING ON GLOVES AND ITS
EFFECTS ON THE SKIN**



FORWARD

Gloves are an important tool that protect the hands of wearer from various hazards. And depending on the profession, glove usage differs from handling infectious hazardous materials of biological origin to handling corrosive, toxic chemicals, or for protection against physical hazards such as sharp objects or very hot and cold materials. Even while wearing gloves, it is essential to understand the parameters which affect glove usage.

When wearing a normal pair of gloves, users can experience discomfort such as very high humidity and elevated temperature which causes the hands to sweat. And with the accumulated sweat which contains oil, urea, salt and water, and the lack of evaporation, users can develop hydration dermatitis.

The skin under the gloves also usually suffers from lack of oxygen. Some users may also develop contact dermatitis due to potential irritation from glove film.

As such, gloves with **COATS**[®] (Colloidal Oatmeal System) coating is developed to protect the skin underneath the gloves and to ensure that the wearers are comfortable and will continue to use gloves as part of compliance to personal protection equipment.



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(n= 5), Aspen Clinical Research Ltd, Maldon, Essex, United Kingdom. Study sponsored by Hartalega Holdings Sdn Bhd

2. **A CLINICAL STUDY TO MEASURE THE EFFECTS OF COATS® (COLLOIDAL OATMEAL SYSTEM) 0.6% COATING CONCENTRATION BLEND ON THE SKIN VS NON-COATED NITRILE GLOVE (CONTROL): TO DEMONSTRATE THE BENEFITS OF THIS COATING AS A PROTECTANT; AND ITS REPARATIVE ROLE ON DAMAGED SKIN**

(n= 11), Aspen Clinical Research Ltd, Maldon, Essex, United Kingdom. Study sponsored by Hartalega Sdn Bhd



**1. A CLINICAL STUDY
TO DEMONSTRATE COATS®
(COLLOIDAL OATMEAL SYSTEM)
EFFICACY AS A SKIN
PROTECTANT, AND HAVING A
REPARATIVE ROLE ON DAMAGED
SKIN BY USING COATS® OF
2 DIFFERENT CONCENTRATIONS
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A CLINICAL STUDY TO DEMONSTRATE COATS® (COLLOIDAL OATMEAL SYSTEM) EFFICACY AS A SKIN PROTECTANT, AND HAVING A REPARATIVE ROLE ON DAMAGED SKIN BY USING COATS OF 2 DIFFERENT CONCENTRATIONS VS CONTROL GROUP

(n= 5), Aspen Clinical Research Ltd, Maldon, Essex, United Kingdom.

OBJECTIVE

To measure the efficacy of **COATS®** - Colloidal Oatmeal System at two different concentrations against a control site for the effect on the skin as a reparative and protective product using instrumental and visual assessments.

STUDY DESIGN

5 healthy volunteers of 18 years old and above were recruited and enrolled in a week, centre based study in Maldon, Essex, United Kingdom.

On day 0, subjects underwent a lead-in phase of a 24 hour pre-irritation patches consisting of 0.5% SLS at the three study sites on the volar forearms.

All subjects completed the study, and no adverse events or reactions were reported.

Evaluations included profilometry, TEWL (transepidermal water loss), Corneometer, and visual assessments of each of the three test sites on the volar forearms at Day 1 and Day 5.



RESULTS

CORNEOMETER assessment of skin hydration.

Moisturisation measurements to study the humectant properties of the Coats blend were performed using the Corneometer CM825 (Courage and Khazaka, Germany).

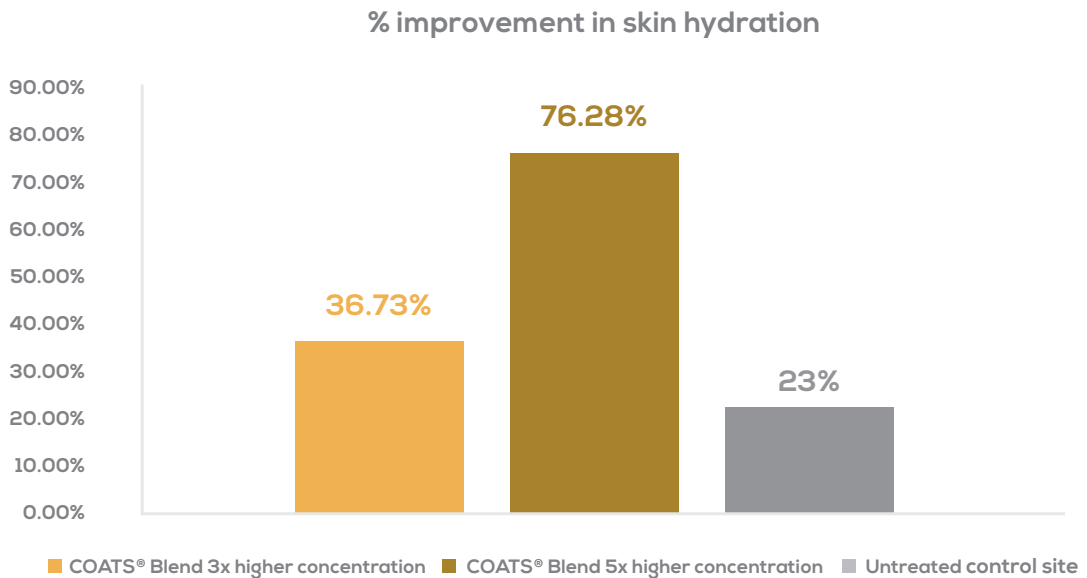
Moisturization measurements showed a significant increase in skin hydration during the study phase for both products concentration.

COATS® blend of 5X higher concentration showed the highest skin hydration, an improvement of 76.28%.

COATS® blend of 3X higher concentration showed skin hydration improvement of 36.73%.

The untreated control group showed the least skin hydration with improvement of 23%.

Percentage improvements in CORNEOMETER (Skin hydration level)



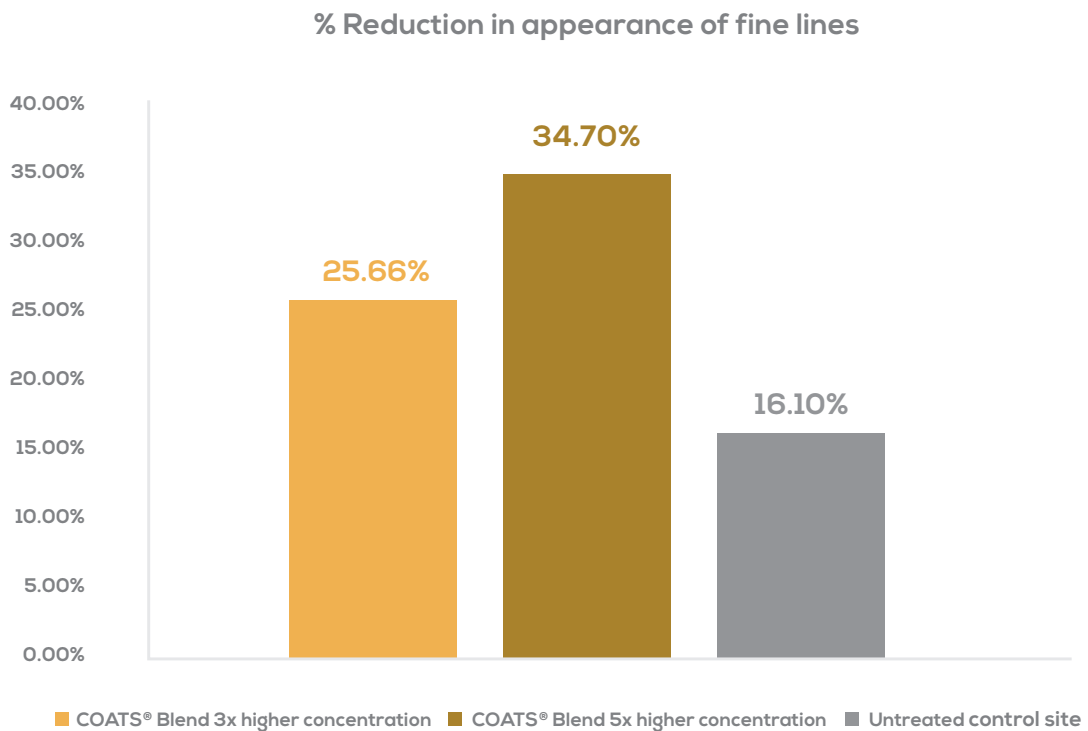
PROFILOMETERY ASSESSMENTS of texture sensitive to fine lines

Parallel sampling orientation were used and it provided texture measurements sensitive to the MINOR, fine lines.

These data showed that **COATS®** blend with 5X higher concentration has the highest reduction in the appearance of fine lines by 34.70%.

COATS® blend with 3X higher concentration, also helped with reduction in the appearance of fine lines by 25.66%.

The untreated control site showed the least reduction in the appearance of fine lines by 16.01%.



TEWAMETER ASSESSMENTS OF TEWL (Transepidermal Water Loss)

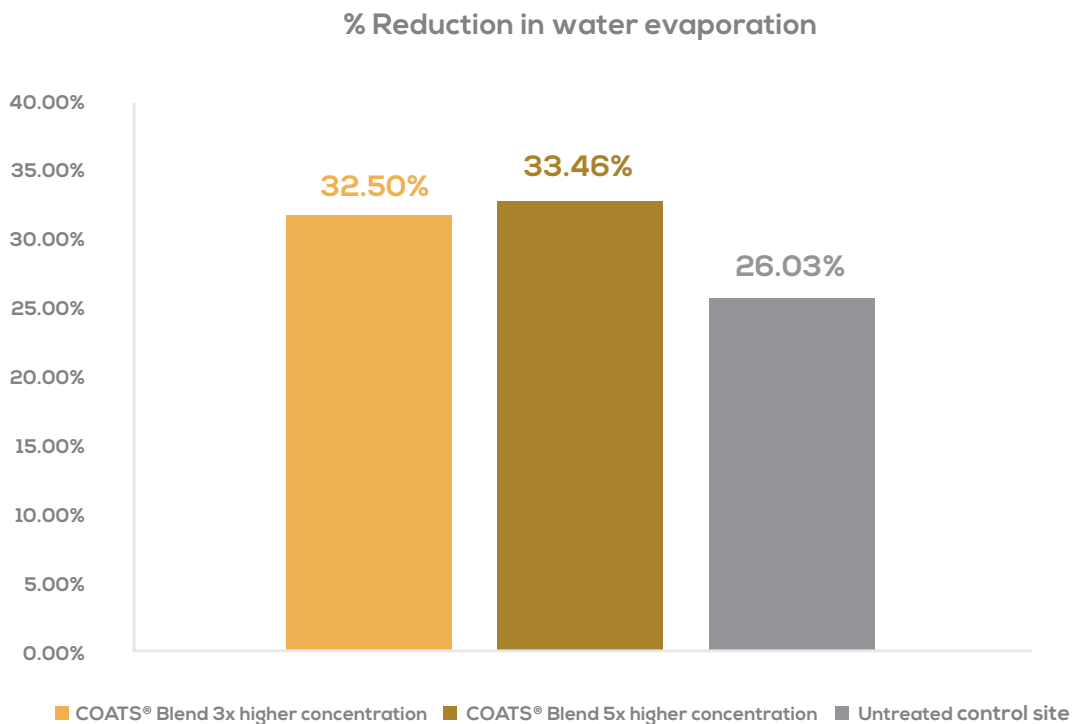
Measurement of water evaporation to study the test articles effect on the skin barrier functionality was performed using the Tewameter TM300 (Courage and Khazaka, Germany).

When TEWL reading is high, it indicates that skin water loss is high which contributes to skin damage.

COATS® blend 5x higher concentration prevented the most water loss, at a reduction of 33.45%.

COATS® blend 3x higher concentration prevented water loss at a reduction of 32.50%.

Untreated control site prevented water loss at a reduction of only 26.03%



VISUAL GRADING ASSESSMENTS

Test sites were graded according to the Visual Assessment Grading Scale. High resolution before and after digital photographs were taken of the test sites area.

Site Photography obtained from 2 subjects

Subject 2

Day 2



Site 1 - COATS® Blend - 3X higher concentration

Results shown moderate erythema with barely perceptible oedema

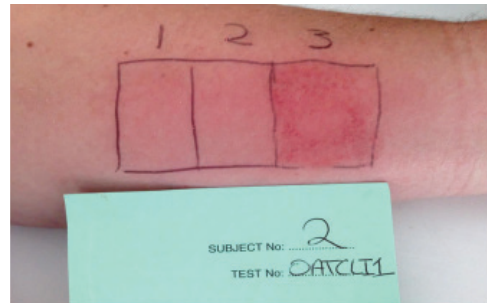
Site 2 - COATS® Blend - 5X higher concentration

Results shown moderate erythema, may have a few papules or deep fissures

Site 3 - Untreated control site

Results shown severe erythema (beet redness), may have generalised papules

Day 6



Site 1 - COATS® Blend - 3X higher concentration

Results shown no apparent cutaneous involvement

Site 2 - COATS® Blend - 5X higher concentration

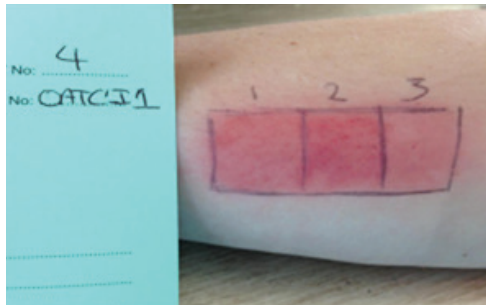
Results shown no apparent cutaneous involvement

Site 3 - Untreated control site

Results shown moderate erythema, may have a few papules

Subject 4

Day 2



Site 1 - COATS® Blend- 3X higher concentration

Results shown moderate erythema, may have a few papules or deep fissures

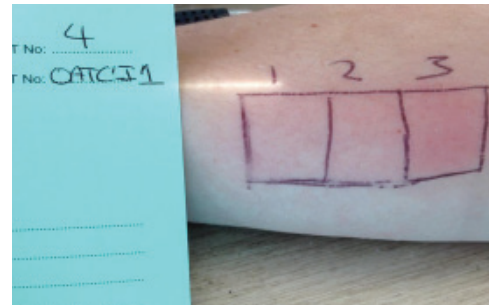
Site 2 - COATS® Blend- 5X higher concentration

Results shown moderate erythema with barely perceptible oedema

Site 3 - Untreated control site

Results shown well defined erythema or faint erythema with definite dryness, may have epidermal fissuring

Day 6



Site 1 - COATS® Blend- 3X higher concentration

Results shown no apparent cutaneous involvement

Site 2 - COATS® Blend- 5X higher concentration

Results shown no apparent cutaneous involvement

Site 3 - Untreated control site

Results shown faint but definite erythema, no eruptions or broken skin, or No erythema but definite dryness, may have epidermal fissuring

Results shown that skin treated with **COATS®** Blend of 3X and 5X higher concentration improved visually at day 6 with no apparent cutaneous involvement. While untreated control site still shown faint to moderate erythema.

CONCLUSIONS

Results from the data and site photography of all the sites were compromised at Day 2 of the study. Following use, both **COATS®** blend with 3X and 5X higher concentration produced results suggesting a return to healthy values and possibly an improvement to the original skin. This cannot be commented on fully as there was no pre-irritation assessments in this preliminary study.

However, the data does suggest that following use of both the **COATS®** (Colloidal Oatmeal System) blend of 3X and 5X higher concentration that there is an improvement to skin moisturisation, skin barrier functionality by preventing water loss, and lessen in the depth of skin fissures and fine lines.

The data can be considered as valid due to the untreated control site returning showing values indicating repair at a much lower rate than that of both the test articles.

COATS® (Colloidal Oatmeal System) blend at 5X higher concentration showed the greatest level of hydration, skin barrier repair and improvement to fissures and wrinkles.



2. A CLINICAL STUDY TO MEASURE THE EFFECTS OF COATS® (COLLOIDAL OATMEAL SYSTEM) 0.6% COATING CONCENTRATION BLEND ON THE SKIN VS NON-COATED NITRILE GLOVE (CONTROL): TO DEMONSTRATE THE BENEFITS OF THIS COATING AS A PROTECTANT; AND THE REPARATIVE ROLE ON DAMAGED SKIN



A CLINICAL STUDY TO MEASURE THE EFFECTS OF COATS® 0.6% COATING CONCENTRATION BLEND ON THE SKIN VS NON-COATED NITRILE GLOVE (CONTROL): TO DEMONSTRATE THE BENEFITS OF THIS COATING AS A PROTECTANT; AND THE REPARATIVE ROLE ON DAMAGED SKIN

(n= 11), Aspen Clinical Research Ltd, Maldon, Essex, United Kingdom

OBJECTIVE

To measure the effects of **COATS®** (Colloidal Oatmeal System) 0.6% coating concentration blend on the skin vs Non-Coated Nitrile Gloves (Control): To demonstrate the benefits of this coating as a protectant; and the reparative role on damaged skin using instrumental and visual assessments.

STUDY DESIGN

5 volunteers- 4 mildly atopic and 1 healthy volunteer of 18 years old and above were recruited and enrolled in an 11 days centre based study in Maldon, Essex, United Kingdom.

All subjects underwent a washout (pre-irritation) phase of 3 days (Day -3 to Day 0) to create a baseline. During this washout phase, subjects worn non coated nitrile gloves over 7 cycles in an 8 hour period with 1 hour break to mimic lunch.

During active phase of 0 hour to 56 hours, subjects wore **COATS®** coated gloves vs non-coated nitrile gloves (control) as instructed over 7 cycles in an 8 hour period with 1 hour break to mimic lunch.

All subjects completed the study, and no adverse events or reactions were reported.

Evaluations included TEWL (transepidermal water loss) and Corneometer of the test sites on the volar forearms were done at day -3, day 0, t+3hours, 8hours, 24hours, 27hours, 32hours, 48hours, 51hours, 56hours, 72hours and 96 hours.



RESULTS

CORNEOMETER assessment of skin hydration.

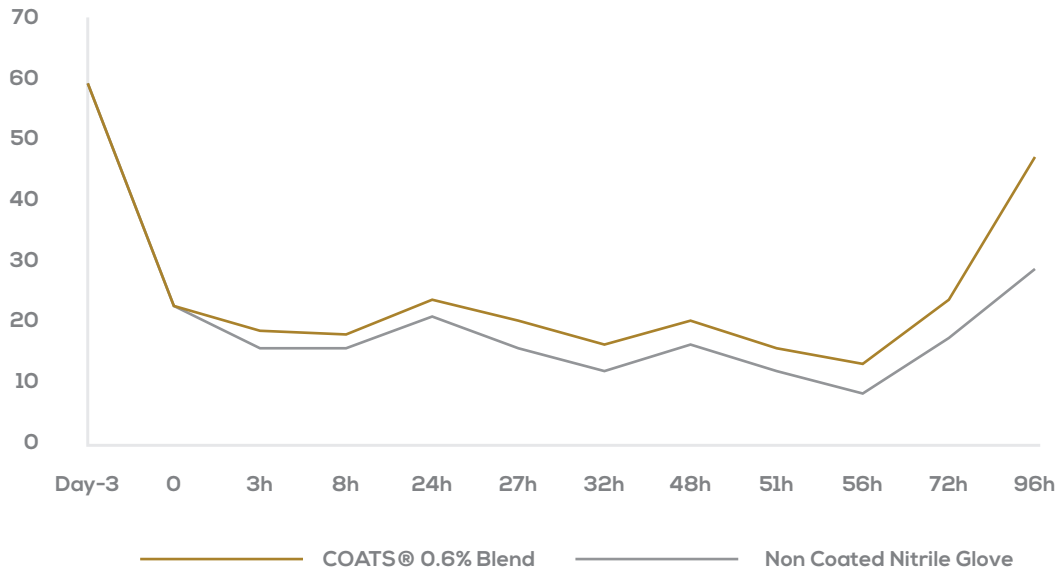
Moisturization measurements to study the humectant properties of the **COATS®** blend were performed using the Corneometer CM825 (Courage and Khazaka, Germany).

COATS® blend 0.6% showed the highest ability to retain skin hydration and with an improvement of 51.48% from baseline.

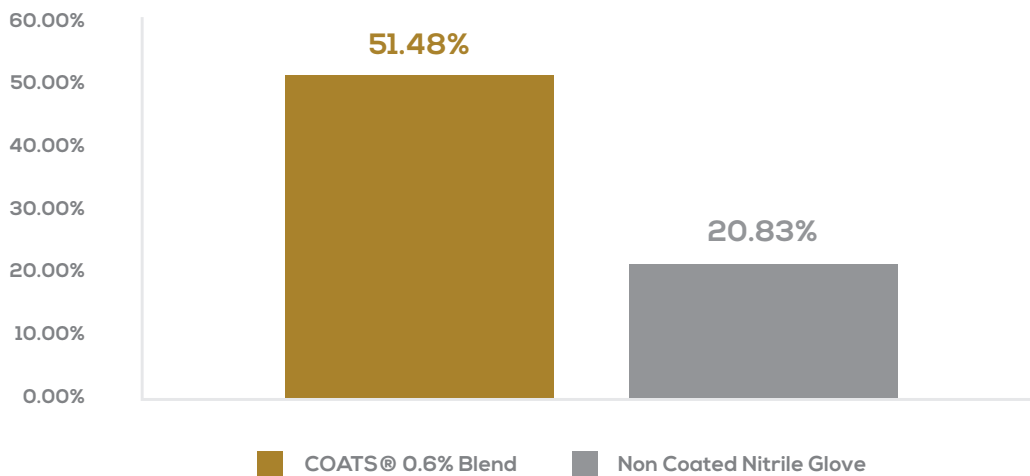
The control group showed a much lower skin hydration retention at 20.83% from baseline.



Corneometer-Moisturization Measurement



% Improvement in skin hydration



TEWAMETER ASSESSMENTS OF TEWL (Transepidermal Water Loss)

Measurement of water evaporation to study the test articles effect on the skin barrier functionality was performed using the Tewameter TM300 (Courage and Khazaka, Germany).

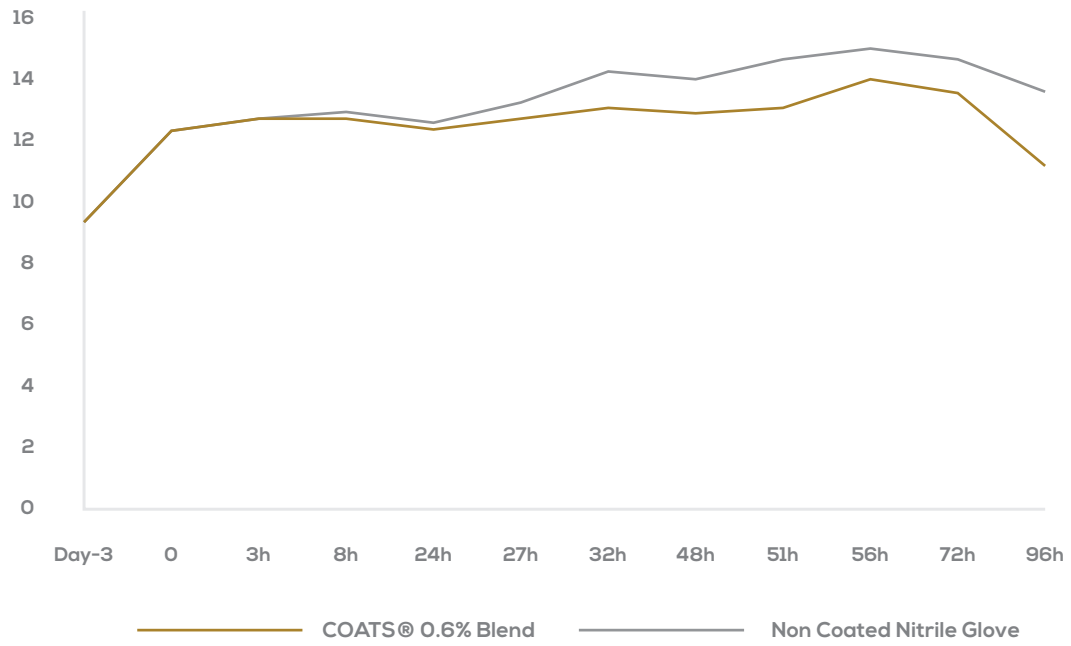
COATS® blend 0.6% showed a 11.94% reduction of water evaporation from baseline.

Non coated nitrile glove showed an increase of 6.05% in water evaporation.

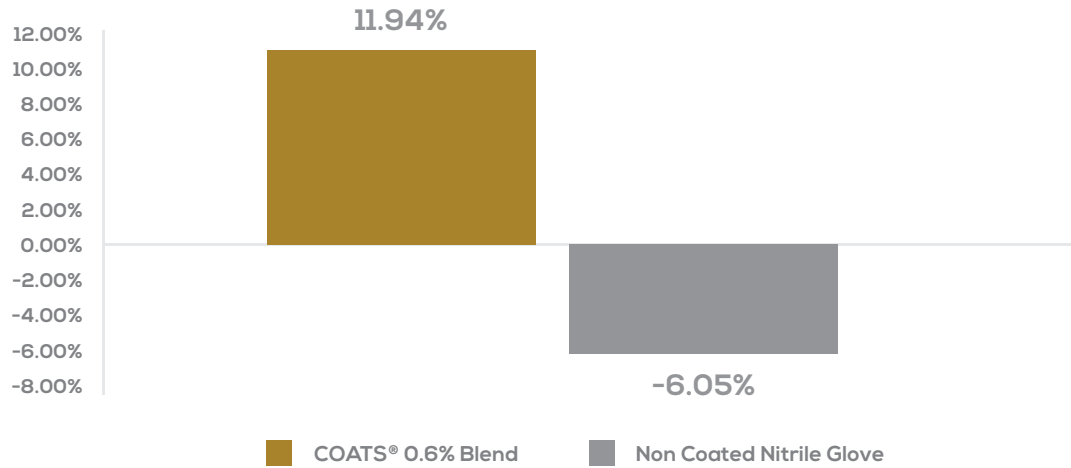
It is critical to note that the higher the water loss, the higher the likelihood for skin damage.



Tewameter - Water evaporation measurements



% Reduction in water evaporation



CONCLUSIONS

COATS® 0.6% Concentration showed a statistically significantly faster return towards baseline values for both skin barrier functionality and skin moisture content compared to the control group.

The treatment group prevented the skin barrier from entering a compromised state according to Transepidermal water loss measurements compared to control site which became compromised in all study groups.

The atopic and healthy type subjects showed no statistical differences in grades for the assessment type under any treatment. It can therefore be concluded that subjects with atopic skin types do not respond differently to the stress placed upon the skin under the study conditions.



APPENDIX

1.0 Profilometry

Profilometry is a measuring instrument for measuring surface's profile in order to determine the surface's roughness, and commonly measured in nanometers.

Different sampling orientation provides texture measurements sensitive to either the major expression-induced lines or minor fine lines. In this study, we are using parallel sampling orientation which provides texture measurements sensitive to fine lines and sites measuring 2.5cm² located on the back of the hands.

2.0 TEWL (Transepidermal Water Loss)

Transepidermal Water Loss (TEWL) measurements to study the test articles effect on the skin barrier functionality was performed using the Tewameter® TM 300 (Courage and Khazaka, Germany). Tewameter® measures water evaporation and therefore TEWL, is based on the diffusion principle in an open chamber. The density gradient measured the temperature and the relative humidity. This density gradient is then analysed by a microprocessor in the instrument.

3.0 Corneometer® assessments of skin hydration

Moisturisation measurements to study the humectant properties of the test articles were performed using the Corneometer® CM825 (Courage and Khazaka, Germany). This measurement relies on the dielectric constant, a physical property of water, which is relatively high and as such will affect the capacitance of a capacitor. Any change in the dielectric constant due to skin moisture variations will alter the capacitance of the precision capacitor in the instrument. These variations are detected electronically and are converted into a value by the Corneometer®.



4.0 Digital photography and image analysis

High resolution digital photographs were taken of the test sites area. And visual assessment were graded using Visual Assessment Grading Scale under standard lighting conditions by the same qualified grader.

Visual Assessment Grading Scale

- 0.0** No apparent cutaneous involvement
- 0.5** Faint, barely perceptible erythema or slight dryness (glazed appearance)
- 1.0** Faint but definite erythema, no eruptions or broken skin or No erythema but definite dryness; may have epidermal fissuring.
- 1.5** Well-defined erythema or faint erythema with definite dryness, may have epidermal fissuring
- 2.0** Moderate erythema, may have a very few papules or deep fissures, moderate-to-severe erythema in the cracks.
- 2.5** Moderate erythema with barely perceptible oedema or severe erythema not involving a significant portion of the patch (halo effect around the edges), may have a few papules of moderate-to-severe erythema.
- 3.0** Severe erythema (beet redness), may have generalised papules or moderate-to-severe erythema with slight oedema (edges well defined by raising).
- 3.5** Moderate-to-severe erythema with moderate oedema (confined to patch area) or moderate-to-severe erythema with isolated eschar formation or vesicles.
- 4.0** Generalised vesicles or eschar formations or moderate-to-severe erythema and/or oedema extending beyond the area of the patch



