

Microshield*

Moisturising Lotion



Skin Moisturisation Study

The moisture retaining effect of MICROSHIELD* Moisturising Lotion New Formulation was tested by corneometer measurements on a panel of 20 volunteers in the course of a 2-hour kinetic investigation.

Test Design

Twenty volunteers were recruited to participate in this study. They were instructed not to use cosmetics on their forearms for three days before the start of the study and during the study. Two areas were tested on each volar forearm. The panelists were instructed not to wash their forearms or take a bath or shower at least two hours prior to beginning of the study.

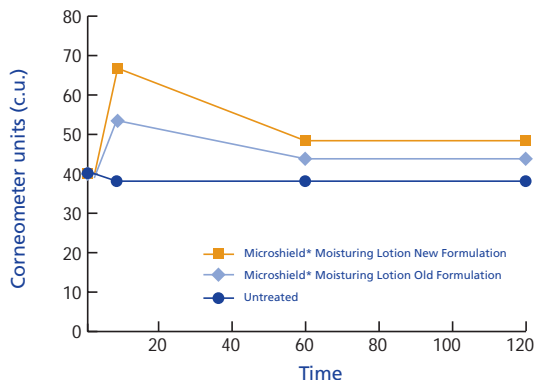
- The volunteers were acclimatised at $22 \pm 1^\circ\text{C}$ room temperature and $50 \pm 5\%$ relative humidity for 45 minutes.
- Before the first product application, a measurement was taken on each test area in order to document the initial reading (five individual measurements per test area).
- The test products were applied once on each test area.
- The measurements were carried out at 5 minutes, 1 hour and 2 hours after product application.

Test Results

In comparison with the untreated area, the test product MICROSHIELD* Moisturising Lotion New Formulation gives higher moisture levels that are statistically significant at 5 min, 1 hour and 2 hour time points.

Summary

MICROSHIELD* Moisturising Lotion New Formulation demonstrates satisfactory moisture retaining capacity and improves the skin moisture level.



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Latex Physical Integrity Tests

An analysis of the physical integrity of latex gloves was conducted to measure glove tear resistance, % elongation at break and tensile strength following 6 hours of direct contact with MICROSHIELD* Moisturising Lotion New Formulation.

Test Design

Latex Glove Tear Resistance Test - Reference: American Society of Testing and Materials. 1991. Standard Test Method D 624 – 91. Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers

Latex Glove Tensile Strength Test - Reference: American Society of Testing and Materials. 1992. Standard Test Method D 412 – 92. Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers – Tension

Latex Glove % Elongation at Break Test - Reference: American Society of Testing and Materials. 1992. Standard Test Method D 412 – 92. Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers – Tension

1. Sections of Powdered Latex Surgical Gloves were treated with the test formulations and conditioned for 6 hours at 30°C. Untreated latex glove sections were also subjected to a similar regimen and act as the untreated negative controls. 2. Using an automated instrument, the tear resistance, tensile strength and % elongation at break were measured at 25°C. The tear resistance is the force per unit glove thickness necessary to tear the latex glove. The tensile strength is the maximum tensile stress needed to stretch the glove until it ruptures. The % elongation at break is the maximum limit to which the glove gets elongated or stretch before it breaks.

Test Result

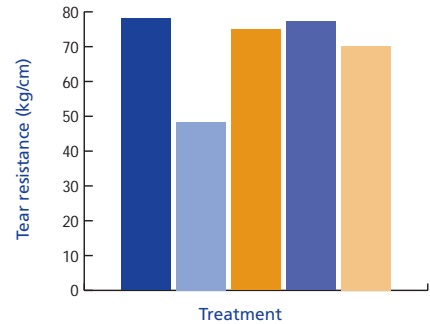
No statistical differences from the untreated negative controls were observed with MICROSHIELD* Moisturising Lotion New Formulation.

Summary

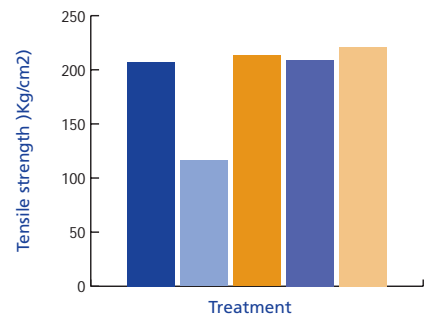
MICROSHIELD* Moisturising Lotion New Formulation does not alter the physical integrity of latex gloves for 6 hours.

MICROSHIELD* Moisturising Lotion New Formulation is safe and compatible for use with latex gloves.

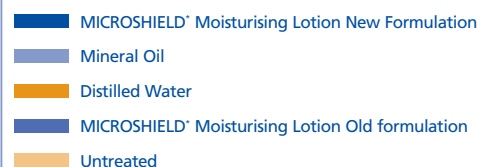
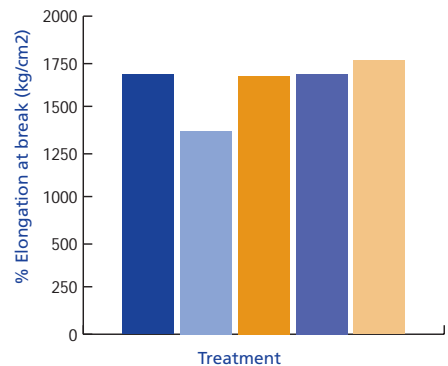
Latex Compatibility Testing - Tear Resistance



Latex Compatibility Testing - Tensile Strength



Latex Compatibility Testing - % Elongation at Break



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Chlorhexidine Gluconate Compatibility Study

The CHG compatibility of MICROSHIELD* Moisturising Lotion New Formulation was assessed by the Glove Juice technique as per the reference - Effects of a protective foam on scrubbing and gloving. AJIC (1993) 21: 297-301 by Larson, E., Anderson, J.K., Baxendale, L. and Bobo, L. The potential for latex glove degradation following lotion use before and after scrubbing was also investigated following a 2-hour wear test.

Test Design:

Test Material	Test Day				
	1	2	3	4	5
Time Period	Immediate	Immediate	Immediate 2 hours	Immediate 2 hours	Immediate 2 hours
Control: 4% CHG	Baseline	Baseline	Surgical Hand Wash	Surgical Hand Wash	Surgical Hand Wash
Treatment: 4% CHG + Lotion	Baseline	Baseline	Surgical Hand Wash + Lotion	Surgical Hand Wash	Surgical Hand Wash + Lotion

- 30 panellists were recruited to participate in a 5 day study modelled on the above reference and summarised in the table.
- Glove-massage recovery technique was performed to gain an estimate of the baseline bacterial population on the hands of each volunteer.
- On Day 3 panellists performed a six-minute surgical hand wash using 10ml 4% chlorhexidine wash. Following the scrub 700mg of MICROSHIELD* Moisturising Lotion was applied. One hand was sampled immediately; the other was tested 2 hours post-hand wash. The 2-hour hand was protected using a powder free latex glove – following removal of the glove, an FDA Watertight Leak Test was performed to assess the impact of the lotion on glove permeability.
- On Day 4 the same procedure was conducted without the application of lotion and the glove wear test was performed.
- On Day 5 the same procedure described in step 3 was performed, however, this time the lotion was applied prior to the surgical scrub. The glove wear test was performed.
- The results were calculated and statistically evaluated for each test day and time period and are presented in the following graph.

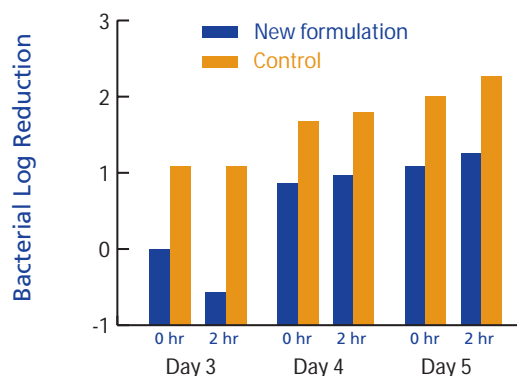
Test Results:

The study quantitatively demonstrated no statistically significant evidence of negative effects on the antimicrobial activity of 4% chlorhexidine gluconate hand wash after scrubbing and no evidence of degradation of powder free latex gloves following a 2 hour wear test.

Summary:

MICROSHIELD* Moisturising Lotion New Formulation demonstrates proven antimicrobial activity with chlorhexidine when used after scrubbing.

MICROSHIELD* Moisturising Lotion New Formulation demonstrates proven latex compatibility following two hours of actual wear.



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Preservative Efficacy

The in vitro antimicrobial preservative activity of MICROSHIELD* Moisturising Lotion New Formulation against Gram positive and Gram-negative bacteria, yeasts and fungi was examined. The study demonstrates the excellent preservative efficacy of Microshield Moisturising Lotion New Formulation.

Test Design

STM # 3061 and 3026. CPWW guidelines WWSP005

Bottles of MICROSHIELD* Moisturising Lotion New Formulation were inoculated twice – once on Day 0, once on Day 7 with known amounts of microbes and incubated.

Samples were taken out at days 2, 7, 14 and 28 after inoculation and aliquots from these were plated to obtain the number of micro-organisms still left viable in the samples.

Summary

MICROSHIELD* Moisturising Lotion New Formulation demonstrated proven antimicrobial preservative efficacy against Gram positive, Gram-negative bacteria as well as yeast and fungal strains.

Skin Safety

Three independent studies were conducted to measure the gentleness of MICROSHIELD* Moisturising Lotion New Formulation following repeated applications.

Test Design

Modified Draize Repeated Insult Patch Test - This test was conducted on 30 subjects to assess the sensitisation potential of the formulation following repeated applications.

Primary Irritation Patch test – This test was conducted on 30 subjects to measure the irritation potential of the formulation following a 48 hour continuous, occlusive exposure.

21-Day Cumulative Irritancy Assay – This test was conducted on 30 human to measure the irritation potential of the formulation following 21 days of occlusive exposure.

Summary

MICROSHIELD* Moisturising Lotion New Formulation demonstrated no evidence of sensitisation and minimal irritation typical of lotion formulations.

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