

# Thermo Scientific SoftGUARD Hand Cream

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## Extra-Strength Barrier Hand Cream

Thermo Scientific SoftGUARD Hand Cream is latex, nitrile, vinyl and CHG compatible. Formula contains an extra-strength preservative system to prevent cross-contamination. SoftGUARD is petroleum, mineral oil and fragrance free and helps prevent the occlusion of the skin. It is non-greasy, absorbs immediately and is pH balanced with the skin.



The unique formulation of Thermo Scientific SoftGUARD helps prevent skin irritation caused by frequent washing and gloving.

### 1. The Extra-Strength Preservative System of SoftGUARD

It is important that hand creams in a healthcare setting have an extra-strength preservative system. This preservative system must be designed to prevent bacterial growth in the unlikely case that the cream is contaminated during use.

SoftGUARD™ has an extra-strength preservative system that combines Methyl Paraben, Propyl Paraben, and Quaternium-15.

Below are the test results of the USP Preservative Effectiveness Test conducted on SoftGUARD. To pass the test, bacteria must be reduced 99.9% by the 14th day, and yeasts and molds (*Candida albicans* and *Aspergillus niger*) must remain at or below the initial count for the entire 28-day period. The first chart of test results to the right demonstrates and confirms the ability of

SoftGUARD to kill both bacteria, yeasts and molds.

To further demonstrate the power of this preservative system, we also

measured percent reduction at 30, 60 and 120 minutes.

These test results which are summarized in the second chart, confirm that SoftGUARD kills bacteria and yeast in minutes, not just days.

### Test: U.S.P. XXII p. 1478. Antimicrobial Preservative Effectiveness Test Data: SoftGUARD Hand Cream

Test Organisms	Initial Inoculum	Day 14 % of Reduction	Day 28 % of Reduction
<i>S.aureus</i> ATCC 6538	1.15 x 10 <sup>6</sup> /ml	>99.99%	>99.99%
<i>E.coli</i> ATCC 8739	3.75 x 10 <sup>6</sup> /ml	>99.99%	>99.99%
<i>Ps.aeruginosa</i> ATCC 9027	2.12 x 10 <sup>6</sup> /ml	>99.99%	>99.99%
<i>C.albicans</i> ATCC 10231	1.70 x 10 <sup>5</sup> /ml	>99.99%	>99.99%
<i>A.niger</i> ATCC 16404	1.0 x 10 <sup>5</sup> /ml	>99.99%	>99.99%
<i>E.coli</i> ATCC 8739	3.75 x 10 <sup>6</sup> /ml	>99.99%	>99.99%
<i>Ps.aeruginosa</i> ATCC 9027	2.12 x 10 <sup>6</sup> /ml	>99.99%	>99.99%
<i>C.albicans</i> ATCC 10231	1.70 x 10 <sup>5</sup> /ml	>99.99%	>99.99%
<i>A.niger</i> ATCC 16404	1.0 x 10 <sup>5</sup> /ml	>99.99%	>99.99%

Test Organisms	Initial Inoculum	30 Minutes % of Reduction	60 Minutes % of Reduction	120 Minutes % of Reduction
<i>S.aureus</i> ATCC 6538	3.1x10 <sup>6</sup> /ml	99.48%	99.74%	99.95%
<i>E.coli</i> ATCC 8739	2.3x10 <sup>6</sup> /ml	80.87%	99.86%	>99.99%
<i>Ps.aeruginosa</i> ATCC 9027	3.0x10 <sup>7</sup> /ml	99.96%	>99.99%	>99.99%
<i>C.albicans</i> ATCC 10231	5.9x10 <sup>7</sup> /ml	>99.99%	>99.99%	>99.99%

(*A.niger* was not reduced after 30, 60 and 120 minutes. It is not expected that a preservative system can kill a fungal spore like *A.niger* in such a short period of time. The fact that SoftGUARD did reduce *A.niger* 99.99% in 14 days far exceeds the USP test criteria. It should be noted that the potential for *A.niger* to be a contaminant in hand cream is extremely remote.)

#### Key Words

- SoftGUARD
- Barrier
- Non-Greasy
- Latex-Compatible
- pH-Balanced

## 2. SoftGUARD and Latex Compatibility

In 1989, Dr. T. Lowe of the Food and Drug Administration (FDA) reported that evidence existed concerning the significant deterioration of latex gloves when gloves were exposed to petroleum-based lubricants. Although little published information exists on this subject, it has become recognized as a serious and legitimate concern. Hand creams containing significant quantities of oil-based ingredients can affect the latex barrier in moments.

The primary effect of such problem ingredients is to plasticize (stiffen) the latex, causing it to break or crack more easily when stretched. This is especially a concern with inherent "thin" spots in a glove. Softening of the latex would be of equal concern. The only way to be sure a cream is latex compatible is proven testing by an independent lab. It is the recommendation of Akron Rubber Development Laboratory, Inc., one of the country's leading rubber testing laboratories, that test method ASTM D 412-92 be used to determine latex compatibility.

This test compares the tensile strength and percent elongation at several stress/strain points (i.e. 100%, 200%, 300%, etc.), as well as the ultimate breaking point. The key is to compare a set of gloves right out of the box versus a set that has been exposed to the given hand cream. Any differences in tensile strength and elongation greater than the normal expected differences between different gloves indicates that plasticizing or softening has occurred as a result of contact with the hand cream.

It is important that this test or similar testing be done prior to the selection of a hand cream that will be used in conjunction with latex gloves. Above right are the test results for SoftGUARD Barrier Hand Cream.

## Effect of SoftGUARD Barrier Hand Cream on Latex Exam Gloves

**Conducted By:** Akron Rubber Development Laboratory

**Test Method:** ASTM D 412-92. Die C Dumbbells prepared from Baxter Latex Exam Gloves and tested at 20 in/min.

**Sample Size:** Thirteen (13) gloves each, exposed and unexposed.

**Exposure Procedure:** Approximately 0.25 to 0.50 ml of the SoftGUARD Barrier Hand Cream was evenly applied to the entire interior surface of each glove. The gloves were then placed into a humidity chamber for 1 hr. @ 95% Relative Humidity @ 99°F. The gloves were then washed in distilled water, dried for no less than 16 hrs. @ 73°F, then tested.

### Unexposed Results

Test Organisms	Tensile Strength, psi (MPa)	Ultimate Elongation, %
Average	4120 (28.4)	867
Median	4212 (29.0)	861
Std. Deviation	261 (1.8)	34

### Exposed to SoftGUARD Results

Test Organisms	Tensile Strength, psi (MPa)	Ultimate Elongation, %
Average	4135 (28.5)	840
Median	4142 (28.6)	834
Std. Deviation	325 (2.2)	42
Percent Change (Avg.)	+0.4	-3.1

**Conclusion:** The effect of SoftGUARD Barrier Hand Cream on the provided gloves was negligible. The small differences were no greater than could be expected from one sampling of gloves to another, therefore, should not be considered as changes caused by the SoftGUARD Barrier Hand Cream.

## 3. SoftGUARD and CHG Compatibility

When a hand cream is used by a staff that wash with a Chlorhexidine Gluconate (CHG) based soap, it is important that the two products are compatible. This means that the cream should not negate the residual or persistent antimicrobial properties of the CHG. Below are test results, which confirm that SoftGUARD does not interfere with CHG bases soaps.

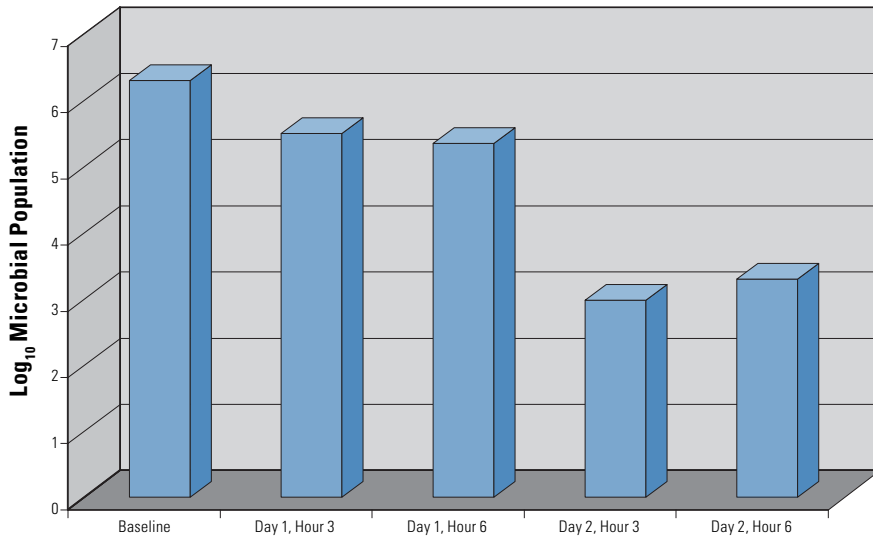
### Surgical Scrub Test

**Procedure:** Six healthy adult volunteers were randomly assigned to one of two study groups. One group used just Hibiclens 4% CHG soap. One group used the same 4% CHG soap but immediately followed each washing with an application of SoftGUARD Barrier

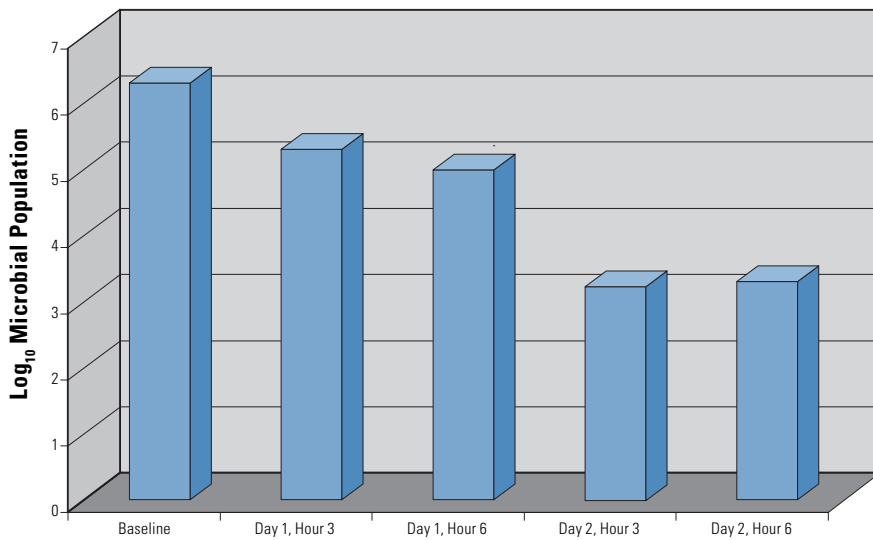
Hand Cream. Baseline microbial counts were determined for each subject. The subjects employed the assigned products five times on day one and three times on day two. The hands were sampled, using the Glove Juice Technique, after the first scrub and/or scrub/cream application on day one, and after the third scrub and/or scrub/cream application on day two.

## Surgical Scrub Test Data

### 4% CHG Soap



### 4% CHG Soap and SoftGUARD



**Conclusion:** The data clearly demonstrates that the 4% CHG Soap with SoftGUARD is equivalent to the 4% CHG soap alone, for both persistent and residual antimicrobial properties. Based on the results, SoftGUARD Barrier Hand Cream does not interfere with the antimicrobial efficacy of CHG based soaps.

#### 4. Other Technical Information for SoftGUARD

SoftGUARD meets OSHA requirements as OSHA permits the use of hand creams in work areas to prevent the irritation caused by frequent gloving and hand washing (p. 64119 of Final Rule). OSHA also warns against petroleum based products that could break down the barrier properties of the glove. SoftGUARD is petroleum free and has been thoroughly tested to insure that it will not affect the integrity of latex gloves (see section 2 for SoftGUARD and Latex Compatibility).

Separately, OSHA reg [d][3][iii] requires labs to provide a product that will help alleviate employee's allergic reactions to gloves. Using SoftGUARD before wearing latex gloves puts a protective barrier on the skin to reduce irritation caused by frequent gloving.

Because fragrances are a common allergen and irritant, the formulation of SoftGUARD is fragrance free. Many fragrances can cause skin irritation to users with sensitive skin.



#### Ingredient List:

Inactive Ingredients: Cetyl Alcohol, Dimethicone, Glyceryl Monostearate, Lanolin, Methylparaben, Propylparaben, Purified Water, Quaternium 15, Sodium Lauryl Sulfate, Sorbitol, Zinc Oxide.

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