

# TECHNICAL BULLETIN

## PURELL® Waterless Surgical Scrub Technical Data

INDICATIONS: significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care

**DIRECTIONS:**

- clean under the nails with a nail pick
- nails should be maintained with a 1 millimeter free edge
- place 2 mL of product into palm of one hand
- dip fingertips of opposite hand into the product and work under nails
- spread remaining product evenly over the hands and lower 2/3 of one forearm paying particular attention to the nails, cuticles, and interdigital spaces
- place 2 mL of product into opposite hand and repeat steps above
- allow to air dry completely

### Physical Properties

Active Ingredient: **70% Ethyl Alcohol**

Appearance: **Clear to translucent solution**

Fragrance: **No fragrance**

Form: **Liquid**

pH: **2.7 - 4.0**

### Ingredients

| INCI Name*  | Ingredient Class  |
|---|---|
| <b>Active:</b>  |   |
| <b>Ethyl Alcohol</b>                                      | <b>Antimicrobial Agent</b>                                    |
| <b>Also Contains:</b>                                     |   |
| <b>Water (Aqua)</b>                                       | <b>Carrier</b>  |
| <b>Isopropyl Alcohol</b>                                  | <b>Denaturant</b>   |
| <b>Isopropyl Myristate</b>                                | <b>Emollient</b>  |
| <b>Glycerin</b>   | <b>Skin Conditioning Agent, Humectant</b>                     |
| <b>Diisopropyl Sebacate</b>                               | <b>Emollient, Skin Moisturizer</b>                            |
| <b>Polyquatarnium-37</b>                                  | <b>Thickener, Stabilizer, and Conditioner</b>                 |
| <b>PEG/PPG-20/6 Dimethicone</b>                           | <b>Surfactant, Emulsifying Agent</b>                          |
| <b>Citric Acid</b>  | <b>pH Adjuster</b>  |
| <b>Hydroxypropylcellulose</b>                             | <b>Viscosity Increasing Agent, Film Former, and Emollient</b> |
| <b>Methylchloroisothiazolinone</b>                        | <b>Preservative</b>   |
| <b>Tetradibutyl Pentaerithrityl Hydroxyhydrocinnamate</b> | <b>Antioxidant</b>  |

\*International Nomenclature Cosmetic Ingredient

## Irritancy Data and Allergy Test Results

### 21 Day Cumulative Irritancy Assay with Delayed Challenge

**Objective:** Evaluation of skin irritation potential in humans.

**Description of Test:** Phillips et al (Toxic and Applied Pharmacology 21:369-382) summarizes the method utilized for this evaluation. Fresh materials are applied daily, 6 days per week, for 21 days to the same site (patches were not moved or reapplied on Sundays).

**Independent Laboratory:** RCTS, INC. Irving, TX USA

**Date:** 7 April 2006

**Results:** Average Score = 0.02 (scale 0 – 4); No sensitization occurred.

**Conclusions:** Mild. Product has a low potential for skin irritation and allergic contact dermatitis.

## Human Repeated Insult Patch Test

**Objective:** Determination of the dermal irritation and sensitization potential of the product.

**Description of Test:** Human repeated insult patch test.

**Independent Laboratory:** Clinical Research Laboratories, Inc., Piscataway, N.J.

**Date:** 27 June 2006

**Results:** No visible skin reactions were observed during the induction or challenge phases of the study.

**Conclusions:** Test product demonstrated no potential for eliciting either dermal irritation or sensitization.

## Efficacy Data – *In Vivo*

**Objective:** This study evaluated the antimicrobial effectiveness of one (1) test product and one (1) reference product using *Effectiveness Testing of a Surgical Hand Scrub*, as specified by the Food and Drug Administration (FR 59:116, 17 June 94, pp. 31448-31450).

**Description of Test:** This study evaluated the antimicrobial efficacy of one (1) test product, PURELL Surgical Scrub with Moisturizers,

used in two (2) different application configurations and one reference product with 4% w/w chlorohexidine gluconate. There were a total of fifty-six subjects assigned to one of the three groups. Sampling was performed on Days 1, 3 and 5 of the Baseline Week to establish baseline population values for each subject.  
 BioScience Laboratories, Inc., Bozeman, MT

**Independent Laboratory:**

**Date:** 23 March 2006

**Results:** The test product applied per Test Product Configuration 1 and 2 met all of the critical indices of the study. The reference product met all of the critical indices of the study, as expected.

| Test             | Application Method #1<br>Three separate applications of two mL of test product. | Application Method #2<br>Two separate applications of two mL of test product. | Reference Product           | FDA Acceptance Criteria     |
|------------------|---|---|-----------------------------|-----------------------------|
|                  | Log <sub>10</sub> Reduction   | Log <sub>10</sub> Reduction   | Log <sub>10</sub> Reduction | Log <sub>10</sub> Reduction |
| Day 1, Immediate | 3.08  | 2.31  | 1.35                        | 1                           |
| Day 1, 3 hour    | 2.53  | 2.58  | 1.19                        | >0 <sup>1</sup>             |
| Day 1, 6 hour    | 2.30  | 2.19  | 0.49                        | N/A <sup>2</sup>            |
| Day 2, Immediate | 3.39  | 2.93  | 2.34                        | 2                           |
| Day 2, 3 hour    | 3.09  | 3.00  | 1.70                        | N/A                         |
| Day 2, 6 hour    | 2.51  | 2.47  | 1.33                        | N/A                         |
| Day 5, Immediate | 3.02  | 3.15  | 3.77                        | 3                           |
| Day 5, 3 hour    | 2.99  | 3.14  | 2.93                        | N/A                         |
| Day 5, 6 hour    | 2.64  | 2.88  | 2.75                        | N/A                         |

<sup>1</sup> FDA acceptance criteria = bacterial cell count does not exceed baseline within 6 hours on the first day

<sup>2</sup> N/A: Not applicable

**Conclusions:** Product meets the criteria for a surgical hand scrub.

## Efficacy Data – *In Vitro*

### Time-Kill Evaluation

**Objective:** Evaluate the antimicrobial effectiveness of the product *in vitro*.

**Description of Test:** Fifteen (15) second time-kill evaluations were performed utilizing fifty (50) challenge bacterial and fungal strains. The challenge inoculum was introduced to the test product at time zero; a portion of the sample was removed and placed in neutralizing media at the appropriate time (15 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms.

**Independent Laboratory:** BioScience Laboratories, Inc., Bozeman, MT

**Date:** 23 March 2006

#### Results:

| Challenge Microbe  | ATCC No. | Exposure (seconds) | Percent Reduction |
|--|----------|--------------------|-------------------|
| <i>Acinetobacter baumannii</i>                           | 19606    | 15                 | 99.9999%          |
| <i>Bacillus megaterium</i> (vegetative cells)            | 14581    | 15                 | 99.9999%          |
| <i>Bacteroides fragilis</i>                              | 29762    | 15                 | 99.9999%          |
| <i>Burkholderia cepacia</i>                              | 25416    | 15                 | 99.9999%          |
| <i>Campylobacter jejuni</i>                              | 29428    | 15                 | 99.9999%          |
| <i>Citrobacter freundii</i>                              | 8090     | 15                 | 99.9999%          |
| <i>Clostridium difficile</i> (vegetative cells)          | 9689     | 15                 | 99.9994%          |
| <i>Clostridium perfringens</i> (vegetative cells)        | 13124    | 15                 | 99.9997%          |
| <i>Corynebacterium diphtheriae</i>                       | 11913    | 15                 | 99.9996%          |
| <i>Enterobacter aerogenes</i>                            | 13048    | 15                 | 99.9999%          |
| <i>Enterococcus faecalis</i> (MDR, VRE)                  | 51575    | 15                 | 99.9999%          |
| <i>Enterococcus faecalis</i>                             | 29212    | 15                 | 99.9999%          |
| <i>Enterococcus faecium</i> (MDR, VRE)                   | 51559    | 15                 | 99.9999%          |
| <i>Escherichia coli</i>                                  | 11229    | 15                 | 99.9998%          |
| <i>Escherichia coli</i>                                  | 25922    | 15                 | 99.9998%          |
| <i>Escherichia coli</i> (O157:H7)                        | 43888    | 15                 | 99.9998%          |
| <i>Haemophilus influenzae</i> MDR                        | 33930    | 15                 | 99.9999%          |
| <i>Klebsiella pneumoniae</i><br>Subsp. <i>ozaenae</i>    | 11296    | 15                 | 99.9999%          |
| <i>Klebsiella pneumoniae</i><br>Subsp. <i>pneumoniae</i> | 13883    | 15                 | 99.9999%          |
| <i>Lactobacillus plantarum</i>                           | 14917    | 15                 | 99.9999%          |
| <i>Listeria monocytogenes</i>                            | 7644     | 15                 | 99.9999%          |

|   |                     |                               |                              |
|---|---------------------|-------------------------------|------------------------------|
| <i>Listeria monocytogenes</i>                           | 15313               | 15                            | 99.9999%                     |
| <i>Micrococcus luteus</i>                               | 7468                | 15                            | 99.9999%                     |
| <i>Proteus mirabilis</i>                                | 7002                | 15                            | 99.9999%                     |
| <i>Proteus vulgaris</i>                                 | 13315               | 15                            | 99.9999%                     |
| <i>Pseudomonas aeruginosa</i>                           | 15442               | 15                            | 99.9999%                     |
| <i>Pseudomonas aeruginosa</i>                           | 27853               | 15                            | 99.9999%                     |
| <i>Salmonella choleraesuis</i><br>Serotype Choleraesuis | 10708               | 15                            | 99.9999%                     |
| <i>Salmonella choleraesuis</i><br>Serotype Enteritidis  | 13076               | 15                            | 99.9999%                     |
| <i>Salmonella choleraesuis</i><br>Serotype Typhimurium  | 14028               | 15                            | 99.9999%                     |
| <i>Serratia marcescens</i>                              | 14756               | 15                            | 99.9999%                     |
| <i>Shigella dysenteriae</i>                             | 13313               | 15                            | 99.9999%                     |
| <i>Shigella sonnei</i>                                  | 11060               | 15                            | 99.9999%                     |
| <i>Staphylococcus aureus</i>                            | 6538                | 15                            | 99.9999%                     |
| <i>Staphylococcus aureus</i>                            | 29213               | 15                            | 99.9999%                     |
| <i>Staphylococcus aureus</i> (MRSA)                     | 33591               | 15                            | 99.9999%                     |
| <i>Staphylococcus aureus</i> (MRSA;PVL+)                | 120805NrS<br>a384*  | 15                            | 99.9999%                     |
| <i>Staphylococcus epidermidis</i>                       | 12228               | 15                            | 99.9999%                     |
| <i>Staphylococcus haemolyticus</i>                      | 43253               | 15                            | 99.9999%                     |
| <i>Staphylococcus hominis</i>                           | 27845               | 15                            | 99.9999%                     |
| <i>Staphylococcus saprophyticus</i>                     | 49453               | 15                            | 99.9999%                     |
| <i>Streptococcus pneumoniae</i>                         | 33400               | 15                            | 99.9999%                     |
| <i>Streptococcus pyogenes</i>                           | 19615               | 15                            | 99.9999%                     |
|   |                     |                               |                              |
|   | <b>ATCC<br/>No.</b> | <b>Exposure<br/>(seconds)</b> | <b>Percent<br/>Reduction</b> |
| <b>Yeasts and Fungi</b>                                 |                     |                               |                              |
| <i>Aspergillus flavus</i>                               | 9643                | 15                            | 99.9540%                     |
| <i>Aspergillus niger</i>                                | 9642                | 15                            | 95.5385%                     |
| <i>Candida albicans</i>                                 | 14053               | 15                            | 99.9999%                     |
| <i>Candida tropicalis</i>                               | 13803               | 15                            | 99.9999%                     |
| <i>Epidermophyton floccosum</i>                         | 52066               | 15                            | 99.9052%                     |
| <i>Penicillium citrinum</i>                             | 9849                | 15                            | 99.9054%                     |
| <i>Trichophyton mentagrophytes</i>                      | 9533                | 15                            | 99.9029%                     |

\*Clinical isolate

Abbreviations: MDR, Multiple drug resistant; VRE, Vancomycin resistant Enterococci; MRSA, Methicillin resistant *Staphylococcus aureus*; PVL, Panton-Valentine Leukocidin;

#### Conclusions:

**Very effective reduction of Gram-negative and Gram-positive bacteria, yeasts and fungi was demonstrated. Therefore the test product exhibits broad spectrum antimicrobial efficacy.**

## Glove Compatibility

|                         |   |
|-------------------------|---|
| <b>Test Method</b>      | <b>ASTM D5151-99</b><br>Glove samples were immersed in product for a period of 2 hours and then examined for leaks. The control samples were not exposed to product.  |
| <b>Testing Lab</b>      | <b>Smithers Scientific Services, Inc, February 14, 2006</b>   |
| <b>Purpose of Study</b> | <b>Determine the effect of product on Surgical Gloves including latex, polyisoprene, latex free neoprene surgical gloves, and a second brand of neoprene surgical gloves.</b>   |
| <b>Sample Size:</b>     | <b>100 control gloves and 100 gloves were tested with PURELL Surgical Scrub with Moisturizers on each of three glove types. Tested were 100 each of latex, polyisoprene, neoprene and a second brand of neoprene surgical gloves.</b> |
| <b>Results:</b>         | <b>In the unexposed control set, there was one leak in the neoprene glove set. There were no leaks in any of the other control or test gloves.</b>  |
| <b>Conclusion:</b>      | <b>The test product does not impact the integrity of latex, neoprene or polyisoprene surgical gloves.</b>   |

### **Compatibility Study To Measure The Effects Of PURELL Surgical Scrub with Moisturizers On The Antimicrobial Properties Of One Chlorhexidine Gluconate Surgical Scrub Formulation**

- Objective:** Assess the compatibility of the test article with a known Chlorhexidine Gluconate (CHG) Surgical Scrub using a modified surgical scrub procedure.
- Description of Test:** The compatibility of the test articles was assessed by comparing the log reductions in baseline bacterial counts of the non-control test configurations to the log reductions of the control configuration.
- Prior to the study, subjects completed a 7 day wash out period to allow the normal microbial population of their hands to stabilize.
- After baseline readings were taken, participants either used the CHG Surgical Scrub product without the test product, used the PURELL Surgical Scrub with Moisturizers prior to washing with the CHG Surgical Scrub

or used the PURELL Surgical Scrub with Moisturizers after washing with the CHG Surgical Scrub product. One hand was tested immediately and the other hand was gloved for two hours and then tested.

**Independent Laboratory:** RCTS, Inc., Irving, TX, USA

**Date:** 14 April 2006

**Results:**

| <b>Configuration</b>   | <b>Baseline</b> | <b>Log Reduction Immediate</b> | <b>Log Reduction at 2 hours</b> |
|--|-----------------|--------------------------------|---------------------------------|
| <b>PURELL Surgical Scrub with Moisturizers followed by use of CHG Surgical Scrub</b> | <b>5.47</b>     | <b>5.06</b>                    | <b>5.01</b>                     |
| <b>CHG Surgical Scrub followed by use of PURELL Surgical Scrub with Moisturizers</b> | <b>5.98</b>     | <b>5.98</b>                    | <b>5.98</b>                     |
| <b>CHG Surgical Scrub (control test)</b>   | <b>5.66</b>     | <b>4.11</b>                    | <b>5.06</b>                     |

**Conclusion**

The log reduction of the test product used before or after the CHG product is not significantly lower than the log reduction of the CHG product when used alone at the immediate and 2 hour time points. Therefore, the test product does not interfere with the antimicrobial efficacy of CHG and is compatible with CHG containing products.

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