

# TECHNICAL BULLETIN

## PURELL<sup>®</sup> FOAMING HAND SANITIZER

### Technical Data

**INDICATIONS:** Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

**DIRECTIONS:** Place 3g of PURELL in your palm and thoroughly cover hands, including between fingers, under fingernails, and around wrists. Rub briskly until dry. No rinsing required.

#### Physical Properties

**Active Ingredient:** 62% Ethyl Alcohol

**Appearance:** White foam

**Fragrance:** Mild alcohol odor

**Form:** Foam

**pH:** 7.0 – 8.0

#### Ingredients

| INCI Name*             | Ingredient Class     |
|------------------------|----------------------|
| <b>Active:</b>         |                      |
| Ethyl Alcohol          | Antimicrobial Agent  |
| <b>Also Contains:</b>  |                      |
| Water (Aqua)           | Carrier              |
| Hydrofluorocarbon 152a | Propellant           |
| Isobutane              | Propellant           |
| Emulsifying Wax NF     | Stabilizer           |
| Cetyl Lactate          | Emollient            |
| Steareth-2             | Emulsifying Agent    |
| Propane                | Propellant           |
| Sodium Benzoate        | Fragrance Ingredient |
| Sodium Sesquicarbonate | pH adjuster          |
| Fragrance (Parfum)     | Fragrance            |

\*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:** 21 Day Cumulative Irritancy Assay with Challenge. Fresh materials are applied daily, 6 days per week, for 21 days to the same site (patches were not moved or reapplied on Sunday).

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

**Date:** 3 January, 2003

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

**Conclusions:** The 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:** 25 February, 2003

**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 a Healthcare Personnel Handwash Procedure, as per methodology specified by the Food and Drug Administration (FR 59:116, 17 June 94, pp. 31448-31450).

**Description of Test:** The antimicrobial effectiveness of one (1) test product and one (1) reference product for use as Health Care Personnel Handwashes was determined using ten (10) consecutive hand contamination/product application procedures. *Serratia marcescens* (ATCC #14756) was the marker organism used for hand contaminations. Eighteen (18) human subjects were utilized for the test and referenced product, for a total of thirty-six (36) subjects. Microbial samples were taken at baseline and after washes one (1), three (3), seven (7), and ten (10). All sampling of the hands was performed using the Glove Juice Sampling Procedure. The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR 59:116, 17 June 94, pp. 31448-31450).

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

**Date:** 22 January, 2003

### Results:

| Wash Number | Reduction from Baseline |
|-------------|-------------------------|
|             | <b>Log<sub>10</sub></b> |
| 1           | 3.29                    |
| 3           | 2.82                    |
| 7           | 2.95                    |
| 10          | 3.12                    |

**Conclusions:** Test product produced statistically significant ( $p < 0.05$ ) Log<sub>10</sub> reductions in bacterial populations from baseline populations of 3.29 after Wash 1 and 3.12 after Wash 10. The critical indices of this study were a two (2) Log<sub>10</sub> reduction after Wash 1 and a three (3) Log<sub>10</sub> reduction after Wash 10. The test product met these criteria.

## Efficacy Data – *In Vitro*

### Timed – Exposure Kill Evaluation

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

**Description of Test:** Fifteen (15) or thirty (30) second exposure kill evaluations were performed utilizing twenty-seven (27) challenge bacterial 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 or 30 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms.

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

**Date:** 28 January, 2003

**Results:**

| Challenge Microbe                                      | ATCC No.      | Exposure (seconds) | Percent Reduction |
|--|---------------|--------------------|-------------------|
| <i>Acinetobacter baumannii</i>                         | 19606         | 15                 | >99.9999          |
| <i>Campylobacter jejuni</i>                            | 29428         | 15                 | >99.9995          |
| <i>Citrobacter freundii</i>                            | 8090          | 15                 | >99.9999          |
| <i>Clostridium difficile</i>                           | 9689          | 15                 | >99.9999          |
| <i>Corynebacterium diphtheriae</i>                     | 11913         | 15                 | >99.9998          |
| <i>Enterobacter aerogenes</i>                          | 13048         | 15                 | >99.9993          |
| <i>Enterococcus faecalis (VRE)</i>                     | 51575         | 15                 | >99.9999          |
| <i>Enterococcus faecium (VRE)</i>                      | 51559         | 15                 | >99.9999          |
| <i>Escherichia coli</i>                                | 11229         | 15                 | >99.9999          |
| <i>Escherichia coli (O157:H7)</i>                      | 35150         | 15                 | >99.9998          |
| <i>Klebsiella pneumoniae</i><br>Subsp.ozaenae          | 11296         | 15                 | >99.9999          |
| <i>Klebsiella pneumoniae</i><br>Subsp.pneumoniae       | 13883         | 15                 | >99.9999          |
| <i>Lactobacillus plantarum</i>                         | 14917         | 15                 | >99.9998          |
| <i>Listeria monocytogenes</i>                          | 15313         | 15                 | >99.9999          |
| <i>Proteus mirabilis</i>                               | 7002          | 15                 | >99.9999          |
| <i>Proteus vulgaris</i>                                | 13315         | 15                 | >99.9983          |
| <i>Pseudomonas aeruginosa</i>                          | 15442         | 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 (MRSA)</i>                    | 33591         | 15                 | >99.9999          |
| <i>Staphylococcus aureus (MRSA)</i>                    | 032301MMRSA4* | 15                 | >99.9999          |
| <i>Staphylococcus epidermidis</i>                      | 12228         | 15                 | >99.9999          |
| <i>Streptococcus pneumoniae</i>                        | 33400         | 15                 | >99.9999          |
| <i>Streptococcus pyogenes</i>                          | 19615         | 15                 | >99.9999          |

\*Clinical Isolate  
MRSA – Methicillin-Resistant *Staphylococcus aureus*