

## TECHNICAL BULLETIN

### PURELL® Advanced Hygienic Hand Sanitising Foam Technical Data

INDICATIONS: Hygienic hand rub to help reduce bacteria on the skin that may be harmful.

METHOD OF USE: Apply approximately 3 mL of PURELL in the palm of your hands, and rub until fully evaporates (circa 30 seconds), without forgetting fingernails, thumbs, between fingers and wrists.

#### Physical Properties

Appearance: **Clear liquid**

Fragrance: **Fragrance Free**

Form: **Liquid dispensed as foam**

INCI Name*
<b>Active:</b>
<b>Ethyl alcohol 70% v/v</b>
<b>Also Contains:</b>
<b>Aqua</b>
<b>Isopropyl Alcohol</b>
<b>PEG-12 Dimethicone</b>
<b>Caprylyl Glycol</b>
<b>Glycerin</b>
<b>Isopropyl Myristate</b>
<b>Tocopheryl Acetate</b>

\*International Nomenclature Cosmetic Ingredient

## Efficacy Data – *In Vivo*

### European Standard EN 1500 (2009-11) Test

<b>Objective:</b>	To evaluate the antimicrobial efficacy of product formulations using the European Standard for Hygienic Handrubs.
<b>Description of Test:</b>	All testing was performed in accordance with EN 1500 (2009-11), the European Standard for testing of a hygienic handrub.
<b>Independent Laboratory:</b>	HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany
<b>Date:</b>	7 February 2011
<b>Results &amp; Conclusions:</b>	The test product when used at 3 ml for 30 seconds fulfills the requirements of EN 1500 (2009-11).

### Healthcare Personnel Handwash

<b>Objective:</b>	This study evaluated the antimicrobial effectiveness of one (1) test product and one (1) control product using a Health-Care Personnel Handwash Procedure, as per methodology specified by the Food and Drug Administration (FR 59:116, 17 Jun 94).
<b>Description of Test:</b>	Twenty-four (24) subjects utilized test product and twenty-four (24) utilized the positive control reference product (48 total). The antimicrobial effectiveness of test product and control product for use as Health-Care Personnel Handwashes were determined using eleven (11) consecutive hand contaminations, the first followed by a sample for baseline, and the remaining ten (10) by product applications. Microbial samples were taken at baseline and after product applications one (1), three (3), seven (7), and ten (10). All sampling of the hands was performed using the Glove Juice Sampling Procedure. <i>Serratia marcescens</i> (ATCC #14756) was the marker organism used for hand contaminations. The FDA requires products to achieve a minimum 2 log <sub>10</sub> reduction after one application and 3 log <sub>10</sub> reduction after 10 applications.
<b>Independent Laboratory:</b>	BioScience Laboratories, Inc., Bozeman, MT, USA
<b>Date:</b>	24 February 2011

**Results:**

Application Number	Test Product Log <sub>10</sub> Reduction	Control Product Log <sub>10</sub> Reduction
1	3.62	2.75
10	4.06	4.52

**Conclusion:** Test product meets FDA Healthcare Personnel Handwash requirements when 2 ml of product is applied to the hands and rubbed in until dry.

### Efficacy Data – *In Vitro*

#### European Standard DIN EN 1276 (01/2010) Test

**Objective:** To determine basic bactericidal activity of test product according to European Norm DIN EN 1276 (01/2010)

**Description of Test:** European Norm DIN EN 1276 (01/2010): Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1)

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 8 September 2010

**Conclusions:** Test product is bactericidal according to European Norm DIN EN 1276 (01/2010) after 15 seconds contact at 20°C under clean conditions (0.03% albumin) versus *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536 and *Pseudomonas aeruginosa* ATCC 15442 at a concentration of 75% (v/v).

#### European Standard EN 13727 (2010-03) Test

**Objective:** To determine bactericidal activity of test product.

**Description of Test:** European Norm EN 13727 (2010-03): Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1).

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 10 September 2010

**Conclusions:** According to EN 13727 (2010-03), the test product

possesses a bactericidal activity under clean conditions (0.03% albumin) in 15 seconds at 20°C for the referenced strains *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* NCTC 10538 and *Pseudomonas aeruginosa* ATCC 15442 when diluted at 75% (v/v) in distilled water.

#### European Standard DIN EN 1040 (March 2006) Test

**Objective:** To determine basic bactericidal activity of test product according to European Norm DIN EN 1040 (March 2006).

**Description of Test:** European Norm DIN EN 1040 (March 2006): Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (phase 1)

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 8 September 2010

**Conclusions:** Test product is bactericidal according to European Norm DIN EN 1040 (March 2006) after 15 seconds contact at 20°C versus *Pseudomonas aeruginosa* ATCC 15442 and *Staphylococcus aureus* ATCC 6538 at a concentration of 75% (v/v).

#### European Standard DIN EN 14348 (April 2005) Test

**Objective:** To determine mycobactericidal activity of test product.

**Description of Test:** European Norm DIN EN 14348 (April 2005): Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1).

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 30 September 2010

**Conclusions:** According to DIN EN 14348 (April 2005), the test product possesses a mycobactericidal activity for the referenced test strains *Mycobacterium terrae* ATCC 15755 and *Mycobacterium avium* ATCC 15769 at 20°C after a contact time of 15 seconds when undiluted.

#### European Standard DIN EN 1275 (March 2006) Test

**Objective:** To determine basic fungicidal activity of test product according to European Norm DIN EN 1275 (March 2006).

**Description of Test:** European Norm EN 1275 (March 2006): Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics (phase 1)

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 8 September 2010

**Conclusions:** Test product is yeasticidal according to European Norm EN 1275 (March 2006) after 15 seconds contact at 20°C versus *Candida albicans* ATCC 10231 at a concentration of 75% (v/v). Test product is fungicidal according to European Norm EN 1275 (March 2006) after 60 seconds contact at 20°C versus *Aspergillus niger* ATCC 16404 at a concentration of 100% (v/v).

#### European Standard EN 13624 (2013) Test

**Objective:** To determine yeasticidal and fungicidal activity of test product.

**Description of Test:** European Norm EN 13624 (2013): Quantitative suspension test for the evaluation of yeasticidal or fungicidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step 1).

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 9 December 2013

**Conclusions:** Test product is yeasticidal according to EN 13624 (2013) under clean conditions (0.03% albumin) in 30 seconds at 20°C versus *Candida albicans* ATCC 10231 at a concentration of 100% (v/v). Test product is fungicidal according to EN 13624 (2013) under clean conditions (0.03% albumin) in 60 seconds at 20°C versus *Aspergillus brasiliensis* ATCC 16404 at a concentration of 100% (v/v).

#### European Standard EN 1650 (May 2008) Test

**Objective:** To determine yeasticidal and fungicidal activity of test product.

**Description of Test:** European Norm EN 1650 (May 2008): Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (phase 2, step 1).

**Independent Laboratory:** HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany

**Date:** 14 March 2013

**Conclusions:** Test product is yeasticidal according to EN 1650 (May 2008) under clean conditions (0.03% albumin) in 30 seconds at 20°C versus *Candida albicans* ATCC 10231 at a concentration of 100% (v/v). Test product is fungicidal according to EN 1650 (May 2008) under clean conditions (0.03% albumin) in 60 seconds at 20°C versus *Aspergillus brasiliensis* ATCC 16404 at a concentration of 100% (v/v).

#### European Standard EN 14476:2007-01 Test

**Objective:** To evaluate the virus-inactivating properties of the test product against non-enveloped viruses adenovirus and poliovirus.

**Description of Test:** European standard EN 14476:2007-01: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics used in Human Medicine (phase 2, step 1)  
MicroBioTest Sterling, VA

**Independent Laboratory:**

**Date:** 30 March 2012

**Conclusions:** According to EN 14476:2007-01, the test product demonstrated effectiveness. It demonstrated a reduction factor (RF) of  $\geq 4.42 \log_{10}$  reduction at 100% dilution against Poliovirus Type 1 after a contact time of 60 seconds and a RF of  $\geq 4.60 \log_{10}$  reduction against Adenovirus Type 5. Therefore, the test product can be declared as virucidal against Poliovirus Type 1 and Adenovirus Type 5.

#### European Standard EN 14476:2007-02 Test

**Objective:** To evaluate the virus-inactivating properties of the test product against murine norovirus (as surrogate for human norovirus).

**Description of Test:** European standard EN 14476:2007-02: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics used in Human Medicine (phase 2, step 1)

**Independent Laboratory:** MikroLab GmbH, Bremen, Germany

**Date:** 22 September 2010

**Conclusions:** According to EN 14476:2007-02, the test product demonstrated effectiveness, with a reduction factor of  $\geq 5.00 \log_{10}$  reduction at 100% dilution against murine norovirus (Berlin 06 / 06 / DE Isolate S99) after a

contact time of 15 seconds. Therefore, the test product can be declared as virucidal against murine norovirus (Berlin 06 / 06 / DE Isolate S99).

#### Virucidal Suspension Efficacy Test Human Influenza A Virus

- Objective:** The study is designed to measure virucidal effectiveness of a test agent. It determines the potential of the test agent to kill Influenza A Virus, A/PR/8/34 (H1N1), in suspension.
- Description of Test:** The test follows the principle outlined in the American Society for Test Materials (ASTM) test method designated E 1052 "Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension." MICROBIOTEST, Inc., Sterling, Virginia USA
- Independent Laboratory:** MICROBIOTEST, Inc., Sterling, Virginia USA
- Date:** 17 March 2011
- Conclusions:** The test product inactivated Human Influenza A virus by  $\geq 6.17$  logs when exposed to the test agent for 15 seconds at 20°C.

#### Virucidal Suspension Efficacy Test SARS-Associated Coronavirus

- Objective:** The study is designed to measure virucidal effectiveness of a test agent. It determines the potential of the test agent to kill SARS-associated Coronavirus, in suspension.
- Description of Test:** The test follows the principle outlined in the American Society for Test Materials (ASTM) test method designated E 1052 "Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension." MICROBIOTEST, Inc., Sterling, Virginia USA
- Independent Laboratory:** MICROBIOTEST, Inc., Sterling, Virginia USA
- Date:** 19 October 2012
- Conclusions:** The test product inactivated SARS-associated Coronavirus by  $\geq 6.17$  logs when exposed to the test agent for 30 seconds at 20°C.

#### Timed – Exposure Kill Evaluation

- Objective:** Evaluate the antimicrobial effectiveness of the product *in vitro*.
- Description of Test:** Fifteen (15) second exposure kill evaluations were performed utilizing fifty-nine (59) challenge microorganism 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:** 19 October 2010, 7 December 2011

**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	99.9824
<i>Bacteroides fragilis</i>	25285	15	99.9913
<i>Burkholderia cepacia</i>	25416	15	99.9999
<i>Burkholderia cepacia</i>	25608	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	99.9943
<i>Clostridium perfringens</i> (vegetative cells)	13124	15	99.9999
<i>Corynebacterium diphtheria</i>	11913	15	99.9999
<i>Enterobacter aerogenes</i>	13048	15	99.9999
<i>Enterococcus faecalis</i>	19433	15	99.9999
<i>Enterococcus faecalis</i>	29212	15	99.9999
<i>Enterococcus faecalis</i> VRE	51299	15	99.9999
<i>Enterococcus faecalis</i> VRE	51575	15	99.9999
<i>Enterococcus faecium</i>	19434	15	99.9999
<i>Enterococcus faecium</i> (MDR, VRE)	51559	15	99.9999
<i>Escherichia coli</i>	11775	15	99.9999
<i>Escherichia coli</i>	25922	15	99.9999
<i>Escherichia coli</i> (O157:H7)	43888	15	99.9999
<i>Escherichia coli</i> (MDR, ESBL)	BAA-196	15	99.9999
<i>Escherichia coli</i> ESBL; Carbapenemase-Producing	BSLI #082710EcC P1	15	99.9998
<i>Haemophilus influenzae</i> MDR	33930	15	99.9999
<i>Klebsiella pneumoniae</i> Ozaenae	11296	15	99.9999
<i>Klebsiella pneumoniae</i> Pneumonia	13883	15	99.9998
<i>Klebsiella pneumoniae pneumoniae</i>	27736	15	99.9998
<i>Klebsiella pneumoniae</i> KPC 2 Positive; Carbapenemase Producing	BSLI#081710 KPCI	15	99.9998
<i>Klebsiella pneumoniae</i> BLA <sub>NDM-1</sub>	BAA-2146	15	99.9999
<i>Lactobacillus plantarum</i>	14917	15	99.9999
<i>Listeria monocytogenes</i>	7644	15	99.9999
<i>Micrococcus luteus</i>	7468	15	99.9992
<i>Proteus hauseri</i>	13315	15	99.9999
<i>Proteus mirabilis</i>	7002	15	99.9999
<i>Pseudomonas aeruginosa</i>	15442	15	99.9999
<i>Pseudomonas aeruginosa</i>	27853	15	99.9999
<i>Salmonella enterica enterica</i> serovar Enteritidis	13076	15	99.9999
<i>Serratia marcescens</i>	8100	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 aureus</i>	6538	15	99.9999
<i>Staphylococcus aureus aureus</i>	29213	15	99.9999
<i>Staphylococcus aureus aureus (MRSA)</i>	33591	15	99.9999
<i>Staphylococcus aureus aureus (MRSA)</i>	33592	15	99.9999
<i>Staphylococcus aureus (MRSA) (VRSA)</i>	BSLI #062707 NARSAVRSa1	15	99.9999
<i>Staphylococcus aureus (MRSA) (NARSA Strain NRS384 USA 300)</i>	BSLI #12085 NRSa384	15	99.9999
<i>Staphylococcus epidermidis</i>	12228	15	99.9999
<i>Staphylococcus epidermidis MRSE</i>	51625	15	99.9998
<i>Staphylococcus haemolyticus</i>	43252	15	99.9998
<i>Staphylococcus hominis hominis</i>	27845	15	99.9997
<i>Staphylococcus saprophyticus</i>	49453	15	99.9999
<i>Streptococcus pneumoniae</i>	6303	15	99.9999
<i>Streptococcus pneumoniae</i>	49619	15	99.9999
<i>Streptococcus pyogenes</i>	14289	15	99.9999
<i>Streptococcus pyogenes</i>	19615	15	99.9999
<b>Yeasts</b>	<b>ATCC No.</b>	<b>Exposure (seconds)</b>	<b>Percent Reduction</b>
<i>Candida albicans</i>	18804	15	99.9999
<i>Candida albicans</i>	66027	15	99.9999
<i>Candida tropicalis</i>	13803	15	99.9999
<b>Fungus</b>	<b>ATCC No.</b>	<b>Exposure (seconds)</b>	<b>Percent Reduction</b>
<i>Aspergillus brasiliensis</i>	9642	15	99.0926
		30	99.9635

**Conclusions:**

**Very effective reduction of gram-negative and gram-positive bacteria and yeasts was demonstrated.**

ESBL- Extended Spectrum Beta-Lactamase Producer

BL<sub>NDM-1</sub>- Beta-Lactamase NDM-1 Producer

MDR – Multi-Drug Resistant

MRSA - Methicillin Resistant *Staphylococcus aureus*

MRSE – Methicillin Resistant *Staphylococcus epidermidis*

NARSA – Network on the Antimicrobial Resistance in *Staphylococcus aureus*

VRE – Vancomycin-Resistant *Enterococcus*

\* - Clinical Isolate

# Irritancy Data and Allergy Test Results

## Human Repeated Insult Patch Test

<b>Objective:</b>	Determination of the dermal irritation and sensitization potential of the product.
<b>Description of Test:</b>	<p>This study was conducted utilizing a standard protocol and a total of fifty-two (52) subjects. Subjects were requested to bathe or wash as usual before arrival at the facility. Patches containing the test material were then affixed directly to the skin of the intrascapular regions of the back, to the right or left of the midline and subjects were dismissed with instructions not to wet or expose the test area to direct sunlight. Subjects were instructed to remove the patches approximately 48 hours after the first application and 24 hours thereafter for the remainder of the study. This procedure was repeated until a series of nine (9) consecutive, 24-hour exposures had been made three (3) times a week for three (3) consecutive weeks. Prior to each reapplication, the test sites were evaluated by trained laboratory personnel. Following a 10-14 day rest period a retest/challenge dose was applied once to a previously unexposed test site. Test sites were evaluated by trained laboratory personnel 48 and 96 hours after application. In the event of an adverse reaction, the area of erythema and edema were measured. Edema is estimated by the evaluation of the skin with respect to the contour of the unaffected normal skin. Subjects were instructed to report any delayed reactions that might occur after the final reading.</p>
<b>Independent Laboratory:</b>	BioScreen Testing Services, Torrance, California, USA
<b>Date:</b>	17 September 2010
<b>Results:</b>	No dermal reactions were observed during the induction or challenge phases of the study.
<b>Conclusions:</b>	Test product did not demonstrate a potential for eliciting dermal irritation or sensitization.

## 21 Day Cumulative Irritancy Assay with Delayed Challenge

<b>Objective:</b>	Evaluation of skin irritation potential in humans.
<b>Description of Test:</b>	Phillips et al (Toxic and Applied Pharmacology 21:369-382) summarizes the method utilized for this evaluation. Fresh materials are applied daily, 5 days per week, for 21 days to the same site (patches were not moved or

**Independent Laboratory:** reapplied on the weekends).  
RCTS, INC. Irving, TX, USA

**Date:** 6 October 2010

**Results:** CIT Average Score = 0.22 (scale 0 – 4; Baby Oil = 0.24)  
Challenge Phase: Non-sensitizing

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

## Compatibility Test Results

### Compatibility Study To Measure The Effects Of The Product On The Antimicrobial Properties Of A Chlorhexidine Gluconate Surgical Scrub Formulation

**Objective:** Assess the compatibility of the test article with a known Chlorhexidine Gluconate (CHG) Surgical Scrub using a pig skin procedure.

**Description of Test:** *Serratia marcescens* ATCC 14756 was used as the indicator organism. The inoculum was applied to sterilized, prepared pigskins and allowed to dry. For baseline samples, skins incubated at room temperature for 2 hours prior to sampling. For the positive control (4% CHG product alone), and test samples (test product applied either before or after a 4% CHG product), products were applied to dried skins then allowed to incubate for 2 hours prior to sampling. Dilutions and plating was done utilizing standard microbiological techniques. Log<sub>10</sub> reductions from baseline were calculated and statistical analysis was conducted to determine whether statistical differences exist between the positive control and the test product samples. A product is considered CHG compatible if the log reduction for the test product in combination with 4% CHG product is not significantly inferior to the positive control.

**Independent Laboratory:** BioScience Laboratories, Bozeman, MT, USA

**Date:** 19 April 2011

**Conclusions:** The log reduction of the test product used before or after the CHG product is not significantly different than the log reduction of the CHG product when used alone. Therefore, the product does not interfere with the antimicrobial efficacy of CHG and is compatible with CHG containing products.

## Glove Compatibility

<b>Test Method</b>	<b>ASTM D5151-99</b> 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 RAPRA Inc., Akron, OH, USA</b>
<b>Date</b>	<b>25 April 2011</b>
<b>Purpose of Study</b>	<b>Determine the effect of product on Medical Gloves including latex, nitrile and vinyl gloves.</b>
<b>Sample Size:</b>	<b>100 control gloves and 100 gloves were tested with the test product on each of three glove types. Tested were latex, vinyl and nitrile gloves.</b>
<b>Results:</b>	<b>The performance of the gloves exposed to the test product was not significantly different to those exposed to the control product.</b>
<b>Summary:</b>	<b>The test product did not significantly impact the integrity of latex, nitrile, and vinyl medical gloves.</b>