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

*International Nomenclature Cosmetic Ingredient

Efficacy Data – *In Vivo*

European Standard EN 1500 (2009-11) Test

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

Healthcare Personnel Handwash

Objective:	**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).**
Description of Test:	**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. *Serratia marcescens* (ATCC #14756) was the marker organism used for hand contaminations. The FDA requires products to achieve a minimum 2 $\log_{10}$ reduction after one application and 3 $\log_{10}$ reduction after 10 applications.**
Independent Laboratory:	**BioScience Laboratories, Inc., Bozeman, MT, USA**
Date:	**24 February 2011**

Results:

Application Number	Test Product Log_{10} Reduction	Control Product Log_{10} 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 Produktsicherhelt 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 Produktsicherhelt 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 Produktsicherhelt 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 (phase2, step 1).
Independent Laboratory:	HygCen Centrum für Hygiene und medizinische Produktsicherhelt 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 Produktsicherhelt 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 Produktsicherhelt 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 Produktsicherhelt 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)**
Independent Laboratory:	**MicroBioTest Sterling, VA**
Date:	**30 March 2012**
Conclusions:	**According to EN 14476:2007-01, the test product demonstrated effectiveness. It demonstrated a reduction factor (RF) of ≥4.42 $\log_{10}$ reduction at 100% dilution against Poliovirus Type 1 after a contact time of 60 seconds and a RF of ≥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 ≥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."**
Independent Laboratory:	**MICROBIOTEST, Inc., Sterling, Virginia USA**
Date:	**17 March 2011**
Conclusions:	**The test product inactivated Human Influenza A virus by ≥ 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."**
Independent Laboratory:	**MICROBIOTEST, Inc., Sterling, Virginia USA**
Date:	**19 October 2012**
Conclusions:	**The test product inactivated SARS-associated Coronavirus by ≥ 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 microoganism 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
Acinetobacter baumannii	19606	15	**99.9999**
Bacillus megaterium (vegetative cells)	14581	15	**99.9824**
Bacteroides fragilis	25285	15	**99.9913**
Burkholderia cepacia	25416	15	**99.9999**
Burkholderia cepacia	25608	15	**99.9999**
Campylobacter jejuni	29428	15	**99.9999**
Citrobacter freundii	8090	15	**99.9999**
Clostridium difficile (vegetative cells)	9689	15	**99.9943**
Clostridium perfringens (vegetative cells)	13124	15	**99.9999**
Corynebacterium diphtheria	11913	15	**99.9999**
Enterobacter aerogenes	13048	15	**99.9999**
Enterococcus faecalis	19433	15	**99.9999**
Enterococcus faecalis	29212	15	**99.9999**
Enterococcus faecalis VRE	51299	15	**99.9999**
Enterococcus faecalis VRE	51575	15	**99.9999**
Enterococcus faecium	19434	15	**99.9999**
Enterococcus faecium (MDR, VRE)	51559	15	**99.9999**
Escherichia coli	11775	15	**99.9999**
Escherichia coli	25922	15	**99.9999**
Escherichia coli (O157:H7)	43888	15	**99.9999**
Escherichia coli (MDR, ESBL)	BAA-196	15	**99.9999**
Escherichia coli ESBL; Carbapenemase-Producing	BSLI #082710EcC P1	15	**99.9998**
Haemophilus influenzae MDR	33930	15	**99.9999**
Klebsiella pneumonia Ozaenae	11296	15	**99.9999**
Klebsiella pneumonia Pneumonia	13883	15	**99.9998**
Klebsiella pneumonia pneumonia	27736	15	**99.9998**
Klebsiella pneumonia KPC 2 Positive; Carbapenemase Producing	BSLI#081710 KPCI	15	**99.9998**
***Klebsiella pneumonia* BLA$_{NDM-1}$**	BAA-2146	15	**99.9999**
Lactobacillus plantarum	14917	15	**99.9999**
Listeria monocytogenes	7644	15	**99.9999**
Micrococcus luteus	7468	15	**99.9992**
Proteus hauseri	13315	15	**99.9999**
Proteus mirabilis	7002	15	**99.9999**
Pseudomonas aeruginosa	15442	15	**99.9999**
Pseudomonas aeruginosa	27853	15	**99.9999**
Salmonella enterica enterica serovar Enteritidis	13076	15	**99.9999**
Serratia marcescens	8100	15	**99.9999**

Serratia marcescens	14756	15	**99.9999**
Shigella dysenteriae	13313	15	**99.9999**
Shigella sonnei	11060	15	**99.9999**
Staphylococcus aureus aureus	6538	15	**99.9999**
Staphylococcus aureus aureus	29213	15	**99.9999**
Staphylococcus aureus aureus (MRSA)	33591	15	**99.9999**
Staphylococcus aureus aureus (MRSA)	33592	15	**99.9999**
Staphylococcus aureus (MRSA) (VRSA)	BSLI #062707 NARSAVRSal	15	**99.9999**
Staphylococcus aureus (MRSA) (NARSA Strain NRS384 USA 300)	BSLI #12085 NRSa384	15	**99.9999**
Staphylococcus epidermidis	12228	15	**99.9999**
Staphylococcus epidermidis MRSE	51625	15	**99.9998**
Staphylococcus haemolyticus	43252	15	**99.9998**
Staphylococcus hominis hominis	27845	15	**99.9997**
Staphylococcus saprophyticus	49453	15	**99.9999**
Streptococcus pneumoniae	6303	15	**99.9999**
Streptococcus pneumoniae	49619	15	**99.9999**
Streptococcus pyogenes	14289	15	**99.9999**
Streptococcus pyogenes	19615	15	**99.9999**
Yeasts	**ATCC No.**	**Exposure (seconds)**	**Percent Reduction**
Candida albicans	18804	15	**99.9999**
Candida albicans	66027	15	**99.9999**
Candida tropicalis	13803	15	**99.9999**
Fungus	**ATCC No.**	**Exposure (seconds)**	**Percent Reduction**
Aspergillus brasiliensis	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
BLA_{NDM-1}- Beta-Lactamase NDM-1 Producer
MDR – Multi-Drug Resistant
MRSA - Methicillin Resistant *Staphylococcus aureus*
MRSE – Methicillin Resistant *Stpaphyococcus epidemidis*
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

Objective:	**Determination of the dermal irritation and sensitization potential of the product.**
Description of Test:	**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.**
Independent Laboratory:	**BioScreen Testing Services, Torrance, California, USA**
Date:	**17 September 2010**
Results:	**No dermal reactions were observed during the induction or challenge phases of the study.**
Conclusions:	**Test product did not demonstrate a potential for eliciting dermal irritation or sensitization.**

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, 5 days per week, for 21 days to the same site (patches were not moved or**

	reapplied on the weekends).
Independent Laboratory:	**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_{10} 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

Test Method	**ASTM D5151-99** **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.**
Testing Lab	**Smithers RAPRA Inc., Akron, OH, USA**
Date	**25 April 2011**
Purpose of Study	**Determine the effect of product on Medical Gloves including latex, nitrile and vinyl gloves.**
Sample Size:	**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.**
Results:	**The performance of the gloves exposed to the test product was not significantly different to those exposed to the control product.**
Summary:	**The test product did not significantly impact the integrity of latex, nitrile, and vinyl medical gloves.**