TECHNICAL BULLETIN

PURELL® Advanced Hygienic Hand Rub
Technical Data

INDICATIONS: Hygienic hand rub to help reduce bacteria on the skin that may be harmful
METHOD OF USE: For Hygienic Hand Rub: 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: Gel
pH: 6.5 – 8.5

INCI Name*
Active:
Ethyl alcohol 70% v/v
Also Contains:
Aqua
Isopropyl Alcohol
Caprylyl Glycol
Glycerin
Isopropyl Myristate
Tocopheryl Acetate
Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Aminomethyl Propanol

*International Nomenclature Cosmetic Ingredient

Efficacy Data – *In Vivo*

European Standard prEN 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 prEN 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:	**6 September 2010**
Conclusions:	**The test product when used at 3 ml for 30 seconds fulfills the requirements of prEN 1500 (2009-11).**

European Standard EN 1500 "Standard Methods of the DGHM for Testing Chemical Disinfection Procedures (Sept. 2001) Test

Objective:	**To evaluate the antimicrobial efficacy of product formulations using the EN 1500 "Standard Methods of the DGHM for Testing Chemical Disinfection Procedures (Sept. 2001) for Hygienic Handrubs.**
Description of Test:	**All testing was performed in accordance with EN 1500 "Standard Methods of the DGHM for Testing Chemical Disinfection Procedures (Sept. 2001).**
Independent Laboratory:	**Priv. Doz. med. Habil. Georg Schrader, Weimar, Germany**
Date:	**13 September 2011**
Conclusions:	**The test product when used at 3 ml for 30 seconds fulfills the requirements of EN 1500 "Standard Methods of the**

DGHM for Testing Chemical Disinfection Procedures (Sept. 2001).

European Standard DIN EN 12791 (October 2005) Test

Objective:	To determine if the test product is suitable for surgical hand disinfection.
Description of Test:	European Norm DIN EN 12791 (October 2005): Test for the evaluation of surgical hand disinfection (phase2, step 2).
Independent Laboratory:	HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH, Schwerin, Germany
Date:	9 February 2012
Conclusions:	According to DIN EN 12791 (October 2005), the test product is suitable for surgical hand disinfection with the additional feature of a sustained effect in the following application: Rub 3ml-portions of product onto the hands and keep them wet for 120 seconds.

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-seven (27) utilized the positive control reference product (51 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: 29 October 2010

Results:

Application Number	Test Product Log_{10} Reduction	Control Product Log_{10} Reduction
1	3.20	3.05
10	3.60	4.76

Conclusions: Test product meets US 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% bovine albumin) versus *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536 and *Pseudomonas aeruginosa* ATCC 15442 at a concentration of 100% undiluted and 75% (v/v).**

European Standard prEN 13727 (2010-03) Test

Objective:	**To determine basic bactericidal activity of test product.**
Description of Test:	**European Norm prEN 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 prEN 13727 (2010-03), the test product possesses a bactericidal activity under clean conditions (0.03% bovine 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 at a**

concentration fo 100% undiluted and 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 100% undiluted and 75% (v/v) diluted.

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:	7 May 2012
Conclusions:	Test product is bactericidal according to European Norm DIN EN 1040 (March 2006) after 15 seconds contact at 20°C versus *Escherichia coli* NCTC 10538 at a concentration of 80% and 75% (v/v) diluted.

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:	**29 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 100% undiluted and 75% (v/v) diluted. 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 prEN 13624 (2010-01) Test

Objective:	**To determine basic fungicidal and yeasticidal activity of test product.**
Description of Test:	**European standard prEN 13624 (2010-01): Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 1)**
Independent Laboratory:	**HygCen Centrum für Hygiene und medizinische Produktsicherhelt GmbH, Schwerin, Germany**
Date:	**17 September 2010**
Conclusions:	**According to prEN 13624 (2010-01) the test product demonstrated fungicidal activity at 20°C under clean conditions (0.3 g/l bovine albumin) in 30 seconds against *Candida albicans* ATCC 10231 and in 60 seconds against *Aspergillus niger* ATCC 16404 at 100% v/v.**

European Standard PN-EN 1650 (2008) Test

Objective:	**To determine basic fungicidal activity of test product.**
Description of Test:	**European standard PN-EN 1650 (2008): Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1)**
Independent Laboratory:	**Test Laboratorium SC, Katowice, Poland**
Date:	**5 June 2011**
Conclusions:	**According to PN-EN 1650 (2008) the test product demonstrated yeasticidal activity at 20°C under clean conditions (0.3 g/l bovine albumin) in 60 seconds against *Candida albicans* ATCC 10231 at 50% and 80% v/v.**

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:	**15 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 a 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).**

European Standard EN 14476+A1:2007-01 Test

Objective:	**To evaluate the virus-inactivating properties of the test product against *poliovirus type 1*.**
Description of Test:	**European standard EN 14476+A1:2007-01: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics used in Human Medicine (phase 2, step 1)**
Independent Laboratory:	**MICROBIOTEST, Sterling, Virginia, USA**
Date:	**20 January 2012**
Conclusions:	**According to EN 14476+A1:2007-01, the test product demonstrated effectiveness, with a reduction factor of ≥4.00 $\log_{10}$ reduction at a 100% dilution against *poliovirus type 1* (Strain LSc-2ab, Eurovir) after a contact time of 60 seconds. Therefore, the test product can be declared as virucidal against *poliovirus.***

European Standard EN 14476+A1:2007-01 Test

Objective:	**To evaluate the virus-inactivating properties of the test product against *adenovirus type 5*.**
Description of Test:	**European standard EN 14476+A1:2007-01: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics used in Human Medicine (phase 2, step 1)**
Independent Laboratory:	**MICROBIOTEST, Sterling, Virginia, USA**
Date:	**20 January 2012**

Conclusions:	**According to EN 14476+A1:2007-01, the test product demonstrated effectiveness, with a reduction factor of ≥5.32 log_{10} reduction at a 100% dilution against *adenovirus type 5* (ATCC VR-5) after a contact time of 30 seconds. Therefore, the test product can be declared as virucidal against *adenovirus type 5* (ATCC VR-5)**

European Standard EN 14476+A1:2007-01 Test

Objective:	**To evaluate the virus-inactivating properties of the test product against *rotavirus*.**
Description of Test:	**European standard EN 14476+A1:2007-01: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics used in Human Medicine (phase 2, step 1)**
Independent Laboratory:	**FONDEREPHAR, Toulouse, France**
Date:	**12 October 2011**
Conclusions:	**According to EN 14476+A1:2007-01, the test product demonstrated effectiveness, with a reduction factor of ≥4.0 log_{10} reduction at a 100% and 40% dilution against *rotavirus* (ATCC VR2272) after a contact time of 30 seconds. Therefore, the test product can be declared as virucidal against *rotavirus* (ATCC VR2272)**

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:	**18 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.

Bovine Viral Diarrhea Virus (BVDV) (Surrogate of Hepatitis C Virus) According to DVV and RKI Virucidal Guideline

Objective:	To evaluate the virus-inactivating properties of the test product against Bovine Viral Diarrhea Virus (BVDV) (Surrogate of Hepatitis C Virus).
Description of Test:	Guideline of DVV and RKI for testing the virucidal efficacy of chemical disinfectants in the medical area (2008)
Independent Laboratory:	MikroLab GmbH, Bremen, Germany
Date:	21 May 2012
Conclusions:	According to the DVV and RKI Guideline, the test product demonstrated effectiveness (≥4-log reduction), undiluted (80%), against BVDV after a contact time of 15 seconds in the presence and absence of protein load (10% fetal bovine serum).

Vaccinia Virus Strain Elstree According to DVV and RKI Virucidal Guideline

Objective:	To evaluate the virus-inactivating properties of the test product against Vaccinia virus strain Elstree.
Description of Test:	Guideline of DVV and RKI for testing the virucidal efficacy of chemical disinfectants in the medical area (2008)
Independent Laboratory:	MikroLab GmbH, Bremen, Germany
Date:	21 May 2012
Conclusions:	According to the DVV and RKI Guideline, the test product demonstrated effectiveness, undiluted (80%), against vaccinia virus after a contact time of 15 seconds in the presence and absence of protein load (10% fetal bovine serum).

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-six (56) 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 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms.**

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

Date: **19 October 2010**

Results:

Challenge Microbe	ATCC No.	Exposure (seconds)	Percent Reduction
Acinetobacter baumannii	19606	15	**99.9999**
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 #082710EcCP1*	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**
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**

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

ESBL- Extended Spectrum Beta-Lactamase 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:	**Human repeated insult patch test.**
Independent Laboratory:	**BioScreen Testing Services, Torrance, California, USA**
Date:	**27 October, 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 = 0.35 (scale 0 – 4; Baby Oil = 0.24) Challenge Phase: Non-sensitizing**
Conclusions:	**Product has a low potential for skin irritation and allergic contact dermatitis.**

Compatibility Test Results

Glove Compatibility

Description of Test:	**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 Scientific Services, Akron, OH, USA**
Date:	**18 October 2010**
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 on each of three glove types. Tested were latex, vinyl and nitrile gloves.**
Results:	**Latex, nitrile, and vinyl gloves exposed to product were not significantly different than the control gloves.**
Summary:	**The test product did not significantly impact the integrity of latex, nitrile and vinyl medical gloves.**

Sensory Test for Potential Taint from Direct Contact with Test Materials (EN ISO 4120:2007)

Objective:	**To determine whether the test product has the potential to taint when exposed to food via hands treated with the test product.**
Description of Test:	**Test is conducted using the EN ISO 4120 Sensory Analysis Triangle Test Methodology (July 2007) using a panel of 42 sensory assessors. In this case the test-product is intended to be used as a leave-on skin sanitiser product. Chocolate was used as the food testing item.**
Independent Laboratory:	**Campden Technology Limited, Gloucestershire, UK.**
Date:	**20 March 2012**
Conclusions:	**The product does not have the potential to taint food when used as a leave-on skin sanitiser.**

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