TECHNICAL BULLETIN

PURELL® Skin Nourishing Foam Hand Sanitiser Technical Data

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

Active Ingredient	**Ethyl Alcohol 70%**
Appearance:	**Colorless, clear liquid**
Fragrance:	**Fragrance free**
Form:	**Liquid, dispensed as foam**

Efficacy Data – European Standards

European Standard EN 1040 Test

Objective:	**To determine basic bactericidal activity of test product according to European Norm EN 1040.**
Description of Test:	**European Norm EN 1040: Chemical disinfectants and antiseptics- Basic bactericidal activity- Test method and requirements (Phase 1).**
Independent Laboratory:	**Hospital Infection Research Laboratory, Birmingham, UK**
Date:	**May 2009**
Conclusions:	**Test product is bactericidal according to European Norm EN 1040 within 1 minute contact at 20°C versus *Pseudomonas aeruginosa* NCTC 6749 and *Staphylococcus aureus* NCTC 10788 at a concentration of 70% and 90%.**

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 DIN 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:	**June 15, 2009**
Conclusions:	**Test product is yeasticidal according to European Norm DIN EN 1275 (March 2006) in 30 and 60 seconds contact at 20°C versus *Candida albicans* ATCC 10231 when diluted at 80% and 75%. Test product is fungicidal according to European Norm DIN EN 1275 (March 2006) in 60 seconds contact at 20°C versus *Aspergillus niger* ATCC 16404 at a concentration of 80%.**

European Standard EN 1500 (1997)Test

Objective:	**To evaluate the antimicrobial efficacy of the test product when compared to the reference product, based on the European Standard for testing of a hygienic handrub, EN 1500 (1997), *Chemical Disinfectants and Antiseptics- Hygienic Handrub-Test Method and Requirements.***
Description of Test:	**European Norm EN 1500 (1997), *Chemical Disinfectants and Antiseptics- Hygienic Handrub-Test Method and Requirements* (phase 2, step 2).**
Independent Laboratory:	**Hospital Infection Research Laboratory, Birmingham, UK**
Date:	**June 2009**
Conclusions:	**The test product when used at 3.2ml for 30 seconds fulfills the requirements of EN 1500 (1997).**

European Standard EN 13727 (2003) Test

Objective:	**To determine basic bactericidal activity of test product.**
Description of Test:	**European Norm EN 13727 (2003): Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used for instruments in the medical area (phase 2, step 1).**
Independent	**Hospital Infection Research Laboratory, Birmingham, UK**

Laboratory:	
Date:	**May 2009**
Conclusions:	**According to EN 13727 (2003), the test product possesses a bactericidal activity under clean conditions (0.03% albumin) in 30 seconds at 20°C for the referenced strains *Pseudomonas aeruginosa* NCTC 6749, *Staphylococcus aureus* NCTC 10788, and *Enterococcus NCTC 12367* at 50%.**

Efficacy Data – Virucidal Suspension Test

Virucidal Suspension Efficacy Test Duck Hepatitis B Virus (Surrogate for Human Hepatitis B virus)

Objective:	**The study is designed to measure virucidal effectiveness of a test agent. It determines the potential of the test agent to kill Duck Hepatitis B virus (DHBV), HepadnaVirus Testing, in suspension.**
Description of Test:	**The test follows the principle outlined in the American Society for Test Materials (ASTM) test method designated E 1052-96 "Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension."**
Independent Laboratory:	**MICROBIOTEST, Inc., Sterling, Virginia USA**
Date:	**May 11, 2009**
Conclusions:	**The test product inactivated Duck Hepatitis B virus by ≥ 3.17 logs when exposed to the test agent for 15 and 30 seconds at 23°C.**

Virucidal Suspension Efficacy Test Respiratory Syncytial Virus

Objective:	**The study is designed to measure virucidal effectiveness of a test agent. It determines the potential of the test agent to kill Respiratory Syncytial Virus, ATCC VR-26, in suspension.**
Description of Test:	**The test follows the principle outlined in the American Society for Test Materials (ASTM) test method designated E 1052-96 "Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension."**
Independent Laboratory:	**MICROBIOTEST, Inc., Sterling, Virginia USA**

Date:	**May 11, 2009**
Conclusions:	**The test product inactivated Respiratory Syncytial Virus by ≥ 3.67 logs when exposed to the test agent for 15 seconds at 34°C.**

Virucidal Suspension Efficacy Test Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)

Objective:	**The study is designed to measure virucidal effectiveness of a test agent. It determines the potential of the test agent to kill Bovine Viral Diarrhea Virus, MDBK cells, ATCC CCL-22, in suspension.**
Description of Test:	**The test follows the principle outlined in the American Society for Test Materials (ASTM) test method designated E 1052-96 "Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension."**
Independent Laboratory:	**MICROBIOTEST, Inc., Sterling, Virginia USA**
Date:	**May 11, 2009**
Conclusions:	**The test product inactivated Bovine Viral Diarrhea Virus by ≥ 3.22 logs when exposed to the test agent for 15 seconds at 21-22°C.**

European Standard EN 14476: 2007-02 Test

Objective:	**To evaluate the virus-inactivating properties of the test product against human rotavirus strain Wa.**
Description of Test:	**European standard EN 14476:2007-02: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics (phase 2, step 1).**
Independent Laboratory:	**MikroLab GmbH, Bremen, Germany**
Date:	**April 30, 2009**
Conclusions:	**According to 14476: 2007-02, the test product demonstrated effectiveness diluted at an 80% test concentration against human rotavirus strain Wa after a contact time of 15 seconds. Therefore, the test product can be declared as virucidal against human rotavirus strain Wa.**

European Standard EN 14476: 2007-02 Test

Objective:	**To evaluate the virus-inactivating properties of the test product against adenovirus type 5.**
Description of Test:	**European standard EN 14476:2007-02: Virucidal Quantitative Suspension Test for Chemical Disinfectants and Antiseptics (phase 2, step 1).**
Independent Laboratory:	**MikroLab GmbH, Bremen, Germany**
Date:	**May 24, 2009**
Conclusions:	**According to 14476: 2007-02, the test product demonstrated effectiveness diluted at a 75% test concentration against adenovirus type 5 after a contact time of 30 seconds. Therefore, the test product can be declared as virucidal against adenovirus type 5.**

Efficacy Data – *In Vitro*

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-seven (57) challenge bacteria 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:	**April 23, 2008**

Results:

Challenge Microbe	ATCC No.	Exposure (seconds)	Percent Reduction
Acinetobacter baumannii	19606	15	**99.9999**
Bacillus megaterium	14581	15	**99.9934**
Bacteroides fragilis	29762	15	**99.9999**
Burkholderia cepacia	25416	15	**99.9999**
Campylobacter jejuni	29428	15	**99.9999**
Citrobacter freundii	8090	15	**99.9999**
Clostridium difficile (vegetative cells)	9689	15	**99.9018**
Clostridium perfringens (vegetative cells)	13124	15	**99.9999**
Corynebacterium diphtheriae	11913	15	**99.9999**
Enterobacter aerogenes	13048	15	**99.9999**

Enterococcus faecalis (MDR, VRE)	51575	15	**99.9999**
Enterococcus faecalis	29212	15	**99.9999**
Enterococcus faecium (MDR, VRE)	51559	15	**99.9997**
Escherichia coli	11229	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**
Haemophilus influenzae MDR	33930	15	**99.9999**
Klebsiella pneumoniae **Subsp.*ozaenae***	11296	15	**99.9999**
Klebsiella pneumoniae **Subsp.*pneumoniae***	13883	15	**99.9999**
Lactobacillus plantarum	14917	15	**99.9999**
Listeria monocytogenes	7644	15	**99.9999**
Listeria monocytogenes	15313	15	**99.9999**
Micrococcus luteus	7468	15	**99.9998**
Proteus hauseri	13315	15	**99.9999**
Proteus mirabilis	7002	15	**99.9999**
Proteus mirabilis (ESBL)	BAA-856	15	**99.9999**
Pseudomonas aeruginosa	15442	15	**99.9999**
Pseudomonas aeruginosa	27853	15	**99.9999**
Salmonella choleraesuis **Serotype Choleraesuis**	10708	15	**99.9999**
Salmonella choleraesuis **Serotype Enteritidis**	13076	15	**99.9999**
Salmonella choleraesuis **Serotype Typhimurium**	14028	15	**99.9999**
Serratia marcescens	14756	15	**99.9999**
Shigella dysenteriae	13313	15	**99.9996**
Shigella sonnei	11060	15	**99.9999**
Staphylococcus aureus	6538	15	**99.9999**
Staphylococcus aureus	29213	15	**99.9999**
Staphylococcus aureus (MRSA)	33591	15	**99.9999**
Staphylococcus aureus (MRSA)	051707 MRSal	15	**99.9999**
Staphylococcus aureus (MRSA)	33593	15	**99.9999**
Staphylococcus aureus (MRSA)	700698	15	**99.9999**
Staphylococcus aureus (MRSA)	700789	15	**99.9999**
Staphylococcus aureus (MRSA) (USA 300)	12085 NRS123	15	**99.9999**
Staphylococcus aureus (MRSA) (USA 400)	081506 SaNRS123	15	**99.9999**
Staphylococcus epidermidis	12228	15	**99.9999**
Staphylococcus haemolyticus	43252	15	**99.9999**
Staphylococcus hominis	27845	15	**99.9999**
Staphylococcus saprophyticus	49453	15	**99.9999**
Streptococcus pneumoniae	33400	15	**99.9983**
Streptococcus pyogenes	19615	15	**99.9999**

Yeasts and Fungi	ATCC No.	Exposure (seconds)	Percent Reduction
Aspergillus flavus	9643	15	**99.9989**
Aspergillus niger	9642	15	**99.9333**
Candida albicans	14053	15	**99.9999**
Candida tropicalis	13803	15	**99.9999**
Epidermophyton floccosum	52066	15	**99.9773**
Penicillium citrinum	9849	15	**99.9511**
Trichophyton mentagrophytes	9533	15	**99.9986**

*Clinical isolate, MDR – multi-drug resistant

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

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 Scientific Services, Inc, 14 March 2008**
Purpose of Study	**Determine the effect of product on Medical Gloves including latex, vinyl and nitrile gloves.**
Sample Size:	**100 control gloves and 100 gloves were tested with PURELL® Instant Hand Sanitizer Skin Nourishing Foam on each of three glove types. Tested were Latex, Vinyl and Nitrile gloves.**
Results:	**There were no leaks detected after product exposure in any of the control or test populations.**
Visual Observation:	**Gloves showed no effect from product exposure.**

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, 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:	**25 October 2007**
Results:	**Average Score = 0.22 (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:	**RCTS, Inc., Irving, Texas, USA**
Date:	**April 18, 2008**
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.**

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