TECHNICAL BULLETIN

PURELL® Advanced Instant Hand Sanitizer Foam
Technical Data

INDICATIONS: Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.
DIRECTIONS: Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

Physical Properties

Appearance: Clear liquid

Fragrance: Fruity fragrance

Form: Liquid dispensed as foam

INCI Name*
Active:
Ethyl alcohol 70% v/v
Also Contains:
Water (Aqua)
Isopropyl Alcohol
PEG-12 Dimethicone
Caprylyl Glycol
Glycerin
Isopropyl Myristate
Tocopheryl Acetate
Fragrance (Parfum)

*International Nomenclature Cosmetic Ingredient

Efficacy Data – *In Vivo*

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-six (26) subjects utilized test product and twenty-four (24) utilized the positive control reference product (50 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

Conclusions: 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*

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 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, 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 #082710EcC P1*	15	**99.9998**
Haemophilus influenzae MDR	33930	15	**99.9999**
Klebsiella pneumonia ozaenae	11296	15	**99.9999**
Klebsiella pneumonia pneumoniae	13883	15	**99.9998**
Klebsiella pneumoniae pneumoniae	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)	062707 NARSAVRSal	15	**99.9999**
Staphylococcus aureus (MRSA) (USA 300)	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

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 = 0.21 (scale 0 – 4; Baby Oil = 0.24) Challenge Phase: Non-sensitizing**
Conclusions:	**Product has a low potential for skin irritation and allergic contact dermatitis.**

Human Repeated Insult Patch Test

Objective:	**To determine the irritation and sensitization (contact allergy) potential of a test material after repeated application to the skin of subjects.**
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, CA, USA
Date:	17 September 2010
Results:	No observed dermal reactions.
Conclusions:	No demonstrated potential for eliciting dermal irritation or sensitization.

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	**6 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:	**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.**