

TECHNICAL BULLETIN

PURELL® Alcohol-Based Gel 85 Technical Data

INDICATIONS: For hygienic and surgical hand disinfection.

DIRECTIONS: For a Hygienic hand rub: Use 3 mL of PURELL in the palm of your hands, and rub until it fully evaporates (circa 30 seconds), without forgetting fingernails, thumbs, between fingers, and wrists.

Physical Properties

Appearance: **Colorless to Pale Yellow**

Fragrance: **Alcoholic, Fragrance Free**

Form: **Gel**

pH: **6.3 - 8.7**

Ingredients

INCI Name*	Ingredient Class
Alcohol	Antimicrobial Agent
Water (Aqua)	Carrier
Isopropyl Alcohol	Denaturant
Acrylates/C10-30 Alkyl Acrylate Crosspolymer	Viscosity Increasing Agent
Aminomethyl Propanol	pH Adjuster
Propylene Glycol	Skin Conditioning Agent, Humectant
Isopropyl Myristate	Emollient

*International Nomenclature Cosmetic Ingredient

Irritancy Data and Allergy Test Results

21 Day Cumulative Irritancy Assay

Objective:	Evaluation of irritation potential in humans.
Description of Test:	Phillips et al. (Toxic and Applied Pharmacology 21: 369-382, 1972). The fresh materials are applied five (5) days weekly for twenty-one (21) days to the same site. Patches are not reapplied on weekends (or holidays); they remain in place for these periods. There are fifteen (15) days of reading, even when holidays intervene.
Independent Laboratory:	Dermatologic Research Laboratory, San Francisco, CA
Date:	March 22, 2002
Results:	Average Score = 0.19 (scale 0 – 4). Lower scores indicate lower potential for skin irritation and allergic contact dermatitis.
Conclusions:	Product has a low potential for skin irritation and allergic contact dermatitis.

Efficacy Data – *In Vitro*

Percent Reduction of Test Organisms After a 15–Second Exposure

Objective: To evaluate the antimicrobial effectiveness of product formulations when challenged with a broad spectrum of microorganisms.

Description of Test: Fifteen (15) second exposure kill studies were performed utilizing twenty-four (24) challenge microorganisms. 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

Dates: May 5, 1995; March 9, 1998; September 4, 1998

Results:

Microorganism	ATCC No.	Percent Reduction
<i>Alcaligenes faecalis</i>	8750	>99.99
<i>Aspergillus niger</i>	16404	>99.99
<i>Bacillus subtilis</i>	6051	>99.98
<i>Branhamella catarrhalis</i>	25238	>99.99
<i>Candida albicans</i>	10231	>99.99
<i>Clostridium difficile</i>	9689	>99.99
<i>Corynebacterium diphtheriae</i>	11913	>99.99
<i>Enterobacter aerogenes</i>	13048	>99.99
<i>Enterococcus faecalis</i> Vancomycin resistant	51575	>99.99
<i>Enterococcus faecium</i> Vancomycin resistant	51559	>99.99
<i>Escherichia coli</i>	11229	99.56
<i>Escherichia coli</i> (O157:H7)	35150	>99.99
<i>Listeria monocytogenes</i>	15313	>99.99
<i>Proteus mirabilis</i>	7002	99.86
<i>Pseudomonas aeruginosa</i>	15442	>99.99
<i>Salmonella enteritidis</i>	13076	>99.99
<i>Salmonella typhimurium</i>	14028	>99.99
<i>Serratia marcescens</i>	14756	>99.99
<i>Shigella dysenteriae</i>	13313	>99.99
<i>Staphylococcus aureus</i> Methicillin resistant	33591	>99.99
<i>Staphylococcus aureus</i>	6538	>99.99

<i>Staphylococcus epidermidis</i>	12228	>99.99
<i>Streptococcus pneumoniae</i>	33400	>99.99
<i>Streptococcus pyogenes</i>	19615	99.95

Conclusions: Very effective reduction of Gram-negative and Gram-positive bacteria was demonstrated.

Efficacy Data – European Standards

European Standard pr EN 12054 (1998 July) Test

Objective: To determine if test product, used for hygienic and surgical handwash, does or does not have bactericidal activity.

Description of Test: European Standard pr EN 12054 (1998 July): Chemical disinfectants and antiseptics- Quantitative suspension test for the evaluation of bacterial activity for hygienic and surgical handrub and handwash used in human medicine- Test method requirements (phase2/ step 1).

Independent Laboratory: ICARE, Saint Beuzire, France

Date: August 12, 2003

Conclusions: According to European standard pr EN 12054 (1998 July), the test product has a bactericidal activity for hygienic handrub at 20°C in 1 minute with a 90% product concentration towards reference strains: *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541, *Escherichia coli* NCTC 10538 and *Staphylococcus aureus* ATCC 6538.

AFNOR Standard NF T 72-180 (December 1989) Test

Objective:	To determine the virucidal activity of test product versus rotavirus SA11 according to an experimental protocol based on AFNOR standard NF T 72-180 (December 1989)
Description of Test:	Performed in accordance with criteria of AFNOR standard NF T 72-180 (December 1989).
Independent Laboratory:	Institut De Recherche Microbiologique, Mitry-Mory, France
Date:	August 7, 2003
Conclusions:	Test product is virucidal versus rotavirus SA11 according to the criteria of AFNOR standard NF T 72-180 (December 1989) after 5 minutes contact at 20°C at a concentration of 50% (w/v).

European Standard NF EN 1040 (April 1997) Test

Objective:	To determine basic bactericidal activity of test product according to European Norm NF EN 1040 (April 1997).
Description of Test:	European Norm NF EN 1040 (April 1997): Chemical disinfectants and antiseptics- Basic bactericidal activity- Test method and requirements (Step 1).
Independent Laboratory:	ICARE, Saint Beauzire, France
Date:	August 12, 2003
Conclusions:	According to the European Standard NF EN 1040 (April 1997) the test product has a bactericidal activity in 1 minute at 20°C with an 80% concentration towards the reference strains <i>Pseudomonas aeruginosa</i> ATCC 15442 and <i>Staphylococcus aureus</i> ATCC 6538.

European Standard NF EN 1275 (June 1997) Test

Objective: To determine if test product does or does not have fungicidal activity.

Description of Test: European Norm NF EN 1275 (June 1997): Chemical disinfectants and antiseptics- Basic fungicidal activity- Test method and requirements (Step 1).

Independent Laboratory: ICARE, Saint Beauzire, France

Date: August 12, 2003

Conclusions: According to the European Standard NF EN 1275 (June 1997) the test product has a fungicidal activity in 5 minutes at 20°C with an 80% concentration towards the reference strain *Candida albicans* ATCC 10231.

European Standard Draft prEN 12791 (1997) Test

Objective: To determine if the test product, for surgical hand disinfection, reduces the release of hand flora according to requirements when used for the disinfection of the clean hands of volunteers.

Description of Test: European Standard Draft EN 12791 (1997): Chemical disinfectants and antiseptics- Surgical hand disinfectants- Test method and requirements (Phase 2/ Step 2).

Independent Laboratory: ICARE, Saint Beauzire, France

Date: August 13, 2003

Conclusions: The average immediate and 3-hour logarithmic reduction factor for the test product are greater than those for the reference product.
According to prEN 12791, the test product is suitable for surgical hand disinfection in the following application: rub as many volumes of 3 mL onto the hands as is necessary to keep them wet for 3 minutes.

Modified European Standard prEN 12054:1995 Test

Objective:	To determine bactericidal activity of product formulations under laboratory conditions (prEN 12054:1995).
Description of Test:	Modified from European Standard prEN 12054: 1995. Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine. Test method requirements (phase2/ step 1).
Independent Laboratory:	Skin Research Centre (Microbiology) University of Leeds, Leeds, United Kingdom
Date:	February 12, 2004
Conclusions:	According to prEN 12054:2001(E), the test product possesses bactericidal activity against <i>Escherichia coli</i> NCTC 10538, <i>Enterococcus hirae</i> NCIMB 8192, <i>Pseudomonas aeruginosa</i> NCIMB 10421 and <i>Staphylococcus aureus</i> NCTC 10788 at 1 minute contact time according to the requirements for a hygienic handrub product.

Modified British Standard prEN 1500:1997 Test

Objective:	To determine whether handrub products reduce the release of transient microflora from artificially contaminated hands.
Description of Test:	Modified from British Standard prEN 1500: 1997. Chemical disinfectants and antiseptics- Hygienic handrub- Test method and requirements (phase 2/ step 2).
Independent Laboratory:	Skin Research Centre (Microbiology) University of Leeds, Leeds, United Kingdom
Date:	April 29, 2004
Conclusions:	According to EN 1500:1997, the test product possesses bactericidal activity against <i>Escherichia coli</i> NCTC 10538 at 30 second contact time equivalent to the reference standard according to the requirements for a hygienic handrub product. According to a modified version EN 1500:1997, the test product revealed bactericidal activity equivalent to the reference standard against <i>Escherichia coli</i> NCTC 10538 after 15 second exposure and against <i>Staphylococcus epidermidis</i> NCTC 11047 after 30 second exposure and after 15 second exposure.

European Standard NF EN 1500 (1997 September) Test

Objective:	To determine if test product allows or does not allow the reduction of transient flora during hygienic handrub.
Description of Test:	European Standard NF EN 1500 (1997 September): Chemical disinfectants and antiseptics- Surgical hand disinfectants- Test method and requirements (phase 2/ step 2).
Independent Laboratory:	ICARE, Saint Beauzire, France
Date:	August 13, 2003
Conclusions:	The average logarithmic reduction factor of the test product is lower than the reference product, but the difference is not statistically significant at significance level $p=0,1$. Test product complies with European Standard EN 1500 (1997 September).