This product may be purchased from Connevans Limited secure online store at www.DeafEquipment.co.uk

TECHNICAL BULLETIN

PURELL® Hygienic Hand Rub
Technical Data

INDICATIONS: Hygienic hand rub to help reduce bacteria on the skin that could cause disease.
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: **Colorless to slightly Yellow**

Fragrance: **Alcoholic, Fragrance Free**

Form: **Gel**

pH: **4.5-9.5**

Ingredients

INCI Name*	Ingredient Class
Alcohol 62%	Antimicrobial Agent
Water (Aqua)	Carrier
Isopropyl Alcohol	Denaturant
Glycerin	Skin Conditioning Agent, Humectant
Carbomer	Viscosity Increasing Agent
Aminomethyl Propanol	pH Adjuster
Propylene Glycol	Skin Conditioning Agent, Humectant
Isopropyl Myristate	Emollient
Tocopheryl Acetate	Skin Conditioning Agent

*International Nomenclature Cosmetic Ingredient

9652-501

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, California, USA**
Date:	**February 27, 1998**
Results:	**Average Score = 0.05 (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.**

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:	**Clinical Research Laboratories, Inc., Piscataway, New Jersey, USA**
Date:	**April 30, 2002**
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.**

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 thirty-four (34) 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, Montana, USA

Dates: March 9, 1998; November 3, 1999; February 9, 2001

Results:

Microorganism	ATCC No.	Percent Reduction
Acinetobacter baumannii	19606	>99.999
Bacillus megaterium	14581	>99.998
Citrobacter freundii	8090	>99.999
Clostridium difficile	9689	99.998
Corynebacterium diphtheriae	11913	>99.999
Enterobacter aerogenes	13048	>99.999
Enterococcus faecalis Vancomycin resistant	51575	>99.999
Enterococcus faecium Vancomycin resistant	51559	>99.999
Escherichia coli	11229	>99.999
Escherichia coli (O157;H7)	35150	>99.999
Klebsiella ozaenae	11296	>99.999
Klebsiella pneumoniae	13883	>99.999
Lactobacillus plantarum	14917	>99.999
Listeria monocytogenes	15313	>99.999
Proteus mirabilis	7002	>99.999
Proteus vulgaris	13315	>99.999
Pseudomonas aeruginosa	15442	>99.999
Salmonella enteritidis	13076	>99.999
Salmonella typhimurium	14028	>99.999
Serratia marcescens	14756	>99.999

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Shigella dysenteriae	13313	>99.999
Shigella sonnei	11060	>99.999
Staphylococcus aureus Methicillin resistant	33591	>99.999
Staphylococcus aureus Vancomycin intermediate Methicillin resistant	Clinical Isolate	>99.999
Staphylococcus epidermidis	12228	>99.999
Streptococcus pneumoniae	33400	99.994
Streptococcus pyogenes	19615	>99.999
Yeasts and Fungi	**ATCC No.**	**Percent Reduction**
Aspergillus flavus	9643	>99.999
Aspergillus niger	9642	>99.998
Candida albicans	14053	>99.999
Candida tropicalis	13803	>99.999
Epidermophyton floccosum	52063	>99.988
Penicillium citrinum	9849	>99.999
Trichophyton mentagrophytes	9533	>99.999

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

Efficacy Data – Virus Testing

Description of Test: A suspension of challenge virus was exposed to the use dilution of the product. An aliquot was removed and neutralized at the thirty (30)- second exposure by serial dilution and then assayed for the presence of viable virus. The following controls were assayed in parallel: positive virus, cytotoxicity and neutralization. Antiviral properties of the product were evaluated and compared at the specified concentration and time interval.

Independent Laboratory: ViroMed Laboratories, Inc., Minneapolis, Minnesota, USA

Date: April 29, 1998; September 23, 1998; September 29, 1998; October 29, 1998; November 4, 1998

Results for Percent Reduction of Test Organisms After a 30-Second Exposure:

Microorganism	ATCC No.	Percent Reduction
Adenovirus type 2	VR-846	95.2
Coxsackievirus B3	VR-30	99.8
Hepatitis A Virus	VR-1073**	94.4
Herpes Simplex Virus Type 1	VR-733	≥99.999
HIV type 1	HTLV-III_B	≥99.993
Influenza Virus Type A_2	VR-544	≥99.9994
Parainfluenza Virus Type 2	VR-92	≥99.996
Parainfluenza Virus Type 3	VR-93	≥99.993
Rhinovirus Type 14	VR-284	99.4
Rhinovirus Type 16	VR-1126	≥99.994
Rhinovirus Type 37	VR-1147	99.82

** Variant 18F

Virus Testing (cont.)

Description of Test: A suspension of challenge virus was exposed to the use dilution of the product. An aliquot was removed and neutralized at the thirty (30)- second exposure by serial dilution and then assayed for the presence of viable virus. The following controls were assayed in parallel: positive virus, cytotoxicity and neutralization. Antiviral properties of the product were evaluated and compared at the specified concentration and time interval.

Independent Laboratory: ATS Labs, Eagan, Minnesota, USA

Date: August 15, 2005

Results for Percent Reduction of Test Organisms After a 30-Second Exposure:

Microorganism	ATCC No.	Percent Reduction
Rotavirus	WA strain	≥99.999

Efficacy Data –
European Standards

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:	**May 14, 2002**
Conclusions:	**Test product is virucidal versus rotavirus SA11 according to the criteria of AFNOR standard NF T 72-180 (December 1989) after 30 seconds contact at 20°C at a concentration of 90% (v/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:	**Institut De Recherche Microbiologique, Mitry-Mory, France**
Date:	**May 6, 1999**
Conclusions:	**Test product is bactericidal according to European Norm NF EN 1040 (April 1997) after 1 minute contact at 20°C versus *Pseudomonas aeruginosa* ATCC 15442 and *Staphylococcus aureus* ATCC 6538 at a concentration of 80% (m/m).**

European Standard NF EN 1275 (June 1997) Test

Objective:	**To determine basic fungicidal activity of test product according to European Norm NF EN 1275 (June 1997).**
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:	**Institut De Recherche Microbiologique, Mitry-Mory, France**
Date:	**May 6, 1999**
Conclusions:	**Test product is fungicidal according to European Norm NF EN 1275 (June 1997) after 5 minutes contact at 20°C versus *Candida albicans* ATCC 10231 at a concentration of 40% (m/m).**

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 *Escherichia coli* NCTC 10538, *Enterococcus hirae* NCIMB 8192, *Pseudomonas aeruginosa* NCIMB 10421 and *Staphylococcus aureus* NCTC 10788 at 1 minute contact time according to the requirements for a hygienic handrub product.**

European Standard prEN 1500 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, the European Standard for testing of a hygienic handrub.**
Independent Laboratory:	**BioScience Laboratories, Inc., Bozeman, Montana, USA**
Date:	**November 24, 1998**
Results & Conclusions:	**The test product was not significantly different from the reference product in reductions of the contaminative bacteria. Therefore, the test product conformed to the product performance requirements of European Standard pr EN 1500, Clause 4.**

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 *Escherichia coli* 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 within test analysis by Wilcoxon signed rank revealed bactericidal activity equivalent to the reference standard against *Staphylococcus epidermidis* NCTC 11047 after 30 second exposure and after 15 second exposure.**

European Standard prEN 1500 Test

Objective:	**To evaluate hygienic hand disinfection of the test product according to the European Standard prEN 1500.**
Description of Test:	**Hygienic hand disinfection according to prEN 1500. 3 mL of test product in dry hands during 15 seconds.**
Independent Laboratory:	**HygCen Centrum für Hygiene und medizinische Produktsicherhelt GmbH, Bischofshofen, Austria**
Date:	**November 21, 2005**
Results & Conclusions:	**The hygienic handrub tests with the test product according to prEN 1500 with a mean reduction factor of 5,14 lg-values is significantly better than the reference method.** **Therefore the test product is effective with the following application recommendations:** **PURELL® Hygienic Hand Rub rubbed into dry hand during 30 seconds.**