TECHNICAL BULLETIN

GOJO® Antibacterial Foam Soap
Technical Data

INDICATIONS: For handwashing to help decrease bacteria on the skin. Recommended for repeated use.
DIRECTIONS: Wet hands with water. Apply approximately 3 ml of product and work into lather for about 30 seconds. Rinse well and dry hands completely.

Physical Properties

Active Ingredient: **0.3% Triclosan**
Appearance: **Clear**
Fragrance: **None**
Form: **Clear Liquid**
pH: **7.8 - 9.7**

Ingredients

INCI Name*	Ingredient Class
Active:	
Triclosan	Antiseptic Agent
Also Contains:	
Aqua	Carrier
Propylene Glycol	Skin Conditioning Agent, Humectant
Alcohol	Solvent
Lauric Acid	Surfactant, Cleansing Agent
Ethanolamine	pH Adjuster
Disodium Cocamphodiacetate	Surfactant, Cleansing Agent, Foam Booster
Lactic Acid	pH Adjuster
Isopropyl Alcohol	Solvent, Denaturant
Tetrasodium EDTA	Chelating Agent
PEG-4	Solvent
Polyquaternium-10	Conditioning Agent
Iodopropynyl Butylcarbamate	Preservative
Sodium Metabisulfite	Antioxidant
Sodium Sulfite	Antioxidant
Tetrasodium EDTA	Chelating Agent
Sodium Sulfate	Viscosity Increasing Agent

*International Nomenclature Cosmetic Ingredient

Efficacy Data –
European Standards

European Standard EN 1499 Test

Objective:	**To determine basic bactericidal activity of test product according to European Norm EN 1499**
Description of Test:	**European Norm EN 1499: Hygienic Handwash.**
Independent Laboratory:	**HygCen Centrum für Hygiene und medizinische Produktsicherhelt GmbH, Schwerin, Germany**
Date:	**29 June 2010**
Conclusions:	**Test product is bactericidal according to European Norm EN 1499 versus *Escherichia coli* NCTC 10538 when approximately 3mL of the product is rubbed on wet hands during 30 seconds.**

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 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:	**15 June 2010**
Conclusions:	**Test product is bactericidal according to European Norm DIN EN 1040 (March 2006) after 30 seconds contact at 20°C versus *Pseudomonas aeruginosa* ATCC 15442 and *Staphylococcus aureus* ATCC 6538 at a concentration of 75% (m/m).**

European Standard DIN EN 1276 (January 2010) Test

Objective:	**To determine basic bactericidal activity of test product according to European Norm DIN EN 1276 (January 2010):**
Description of Test:	**European Norm DIN EN 1276 (January 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:	**15 June 2010**
Conclusions:	**Test product is bactericidal according to European Norm DIN EN 1276 (January 2010) after 30 seconds contact at 20°C under dirty conditions (0.3 % bovine albumine) versus *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536, *Pseudomonas aeruginosa* ATCC 15442 at a concentration of 75% (m/m).**

European Standard prEN 13727 (March 2010) Test

Objective:	**To determine basic bactericidal activity of test product.**
Description of Test:	**European Norm prEN 13727 (March 2010): 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:	**15 September 2010**
Conclusions:	**According to prEN 13727 (March 2010), the test product possesses a bactericidal activity under clean conditions (0.03% g/l albumine) in 30 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 when diluted at 80% (v/v) in distilled water.**

Efficacy Data – *In Vivo*

Objective: This study evaluated the antimicrobial effectiveness of one (1) test products and one (1) reference 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: Eighteen (18) human subjects were utilized per test product (36 total). The antimicrobial effectiveness of one (1) test product and one (1) reference 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 testing methods were based on the Food and Drug Administration 1994 Tentative Final Monograph (TFM) (FR 59:116, 17 Jun 94).

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

Date: 26 July 2006

Results:

Wash	ANTIBACTERIAL Reduction	Reference Reduction
Number	Log_{10}	Log_{10}
1	3.23	2.77
3	3.18	3.44
7	3.27	3.96
10	3.29	4.15

Conclusions: Test product meets the Health-Care Personnel Handwash requirements.

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 forty-nine (49) 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 or 30 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms.

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

Date: 8 September 2006

Results:

Challenge Microbe	ATCC No.	Exposure (seconds)	Percent Reduction
Acinetobacter baumannii	19606	15	**99.8678**
Bacillus megaterium (vegetative cells)	14581	15	**99.9877**
Bacteroides fragilis	29762	15	**99.9203**
Burkholderia cepacia	25416	15	**99.9984**
Campylobacter jejuni	29428	15	**99.9999**
Citrobacter freundii	8090	15	**99.9879**
Clostridium difficile (vegetative cells)	9689	15	**99.8958**
Clostridium perfringens (vegetative cells)	13124	15	**99.8750**
Corynebacterium diphtheriae	11913	15	**99.9957**
Enterobacter aerogenes	13048	15	**99.9935**
Enterococcus faecalis (*MDR, VRE*)	51575	15	**99.9963**
Enterococcus faecalis	29212	15	**99.9899**
Enterococcus faecium (*MDR, VRE*)	51559	15	**99.9853**
Escherichia coli	11229	15	**99.9860**
Escherichia coli	25922	15	**99.9467**
***Escherichia coli* (MDR, ESBL)**	BAA-196	15	**99.9857**
***Escherichia coli* (O157:H7)**	43888	15	**99.9967**
Haemophilus influenzae (*MDR*)	33930	15	**99.9993**

Klebsiella pneumoniae Subsp.*ozaenae*	11296	15	**99.9548**
Klebsiella pneumoniae Subsp.*pneumoniae*	13883	15	**99.9880**
Lactobacillus plantarum	14917	15	**99.9956**
Listeria monocytogenes	7644	15	**99.9950**
Micrococcus luteus	7468	15	**99.9978**
Proteus hauseri (formerly *P. vulgaris*)	13315	15	**99.9924**
Proteus mirabilis	7002	15	**99.9852**
***Proteus mirabilis* (ESBL)**	BAA-856	15	**99.9903**
Pseudomonas aeruginosa	15442	15	**99.9899**
Pseudomonas aeruginosa	27853	15	**99.9865**
Salmonella enterica *enterica* serovar Choleraesius	10708	15	**99.9952**
Salmonella enterica *enterica* serovar Enteritidis	13076	15	**99.9943**
Salmonella enterica *enterica* serovar Typhimurium	14028	15	**99.9929**
Serratia marcescens	14756	15	**99.8781**
Shigella dysenteriae	13313	15	**99.9928**
Shigella sonnei	11060	15	**99.9962**
Staphylococcus aureus	6538	15	**99.9926**
Staphylococcus aureus	29213	15	**99.6453**
***Staphylococcus aureus* (MRSA; GRSA)**	33593	15	**99.9946**
***Staphylococcus aureus* (MRSA; hetero-VISA)**	700698	15	**99.9836**
Staphylococcus epidermidis	12228	15	**99.8233**
Staphylococcus haemolyticus	43253	15	**97.0791**
Streptococcus pneumoniae	33400	15	**99.9951**
Streptococcus pyogenes	19615	15	**99.9946**
Yeasts and Fungi	**ATCC No.**	**Exposure (seconds)**	**Percent Reduction**
Candida albicans	14053	15	**99.7415**
Candida tropicalis	13803	15	**99.9896**

ESBL: Extended spectrum beta-lactamase producer
GRSA: Gentamicin resistant *Staphylococcus aureus*
MDR: Multi-drug resistant
MRSA: Methicillin resistant *Staphylococcus aureus*
VISA : Vancomycin Intermediate *Staphylococcus aureus*
VRE: Vancomycin resistant *Enterococcus*

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, 6 days per week, for 21 days to the same site (patches were not moved or reapplied on Sunday).**
Independent Laboratory:	**RCTS, INC. Irving, TX USA**
Date:	**5 October 2010**
Results:	**Average Score = 0.29 (scale 0 – 4); No sensitization occurred.**
Conclusions:	**Probably mild in use.**

Human Repeated Insult Patch Test

Objective:	**Determination of the dermal irritation and sensitization potential of the product.**
Description of Test:	**Human repeated patch insult test. Patches with test material are applied directly to the skin. Patches are removed 48 hours after the first application and 24 hours thereafter for the remainder of the study. This procedure is repeated until a series of 9 consecutive, 24 hour exposures have been made 3 times a week for 3 consecutive weeks. This is followed by a 10-14 day rest period with a challenge dose applied and examined 48 and 96 hours after application.**
Independent Laboratory:	**BioScreen Testing Services, Inc., Torrance, CA**
Date:	**17 September 2010**

Results:	**No skin reactions were observed during the induction or challenge phases of the study.**
Conclusions:	**Test product did not demonstrate a potential for eliciting either dermal irritation or sensitization.**

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 30 sensory assessors. In this case the test-product is intended to be used as a rinse-off handwash. Chocolate was used as the food testing item.**
Independent Laboratory:	**Campden Technology Limited, Gloucestershire, UK.**
Date:	**1 Nov 2011**
Conclusions:	**The product does not have the potential to taint food when used as a rinse-off product.**