

# 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. Apply a small amount of product and work into a lather. Rinse well and dry hands completely

### Physical Properties

Appearance: **Clear**

Fragrance: **None**

Form: **Liquid**

pH: **7.8 - 9.7**

### Ingredients

INCI Name*	Ingredient Class
Triclosan	Antiseptic Agent
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

\*International Nomenclature Cosmetic Ingredient

## **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:** 6 August 2006

**Results:** Average Score = 0.33 (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 insult patch test.

**Independent Laboratory:** Clinical Research Laboratories, Inc., Piscataway, N.J.

**Date:** 25 August 2006

**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.

## Forearm Controlled Application Test

**Objective:** Determine the mildness of a test product when used for high frequency handwashing using an exaggerated arm wash protocol.

**Description of Test:** Arm is washed with test article for 1 minute over six consecutive washes on four consecutive days, followed by two 1 minute washes for 1 day. Skin hydration/barrier damage, redness and dryness are measured by expert evaluation and dermatological instruments at baseline, day 1, day 3 and day 5.

**Independent Laboratory:** RCTS, Inc. Irving Texas, USA

**Date:** 31 May 2006

**Results:** High frequency use of the test product does not result in significant increases in skin barrier damage, redness or dryness.

**Conclusions:** Test product is mild enough for high frequency handwashing.

## 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 <sub>10</sub>	Log <sub>10</sub>
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
<i>Acinetobacter baumannii</i>	19606	15	99.8678
<i>Bacillus megaterium</i> (vegetative cells)	14581	15	99.9877
<i>Bacteroides fragilis</i>	29762	15	99.9203
<i>Burkholderia cepacia</i>	25416	15	99.9984
<i>Campylobacter jejuni</i>	29428	15	99.9999
<i>Citrobacter freundii</i>	8090	15	99.9879
<i>Clostridium difficile</i> (vegetative cells)	9689	15	99.8958
<i>Clostridium perfringens</i> (vegetative cells)	13124	15	99.8750
<i>Corynebacterium diphtheriae</i>	11913	15	99.9957
<i>Enterobacter aerogenes</i>	13048	15	99.9935
<i>Enterococcus faecalis</i> (MDR, VRE)	51575	15	99.9963
<i>Enterococcus faecalis</i>	29212	15	99.9899
<i>Enterococcus faecium</i> (MDR, VRE)	51559	15	99.9853
<i>Escherichia coli</i>	11229	15	99.9860
<i>Escherichia coli</i>	25922	15	99.9467
<i>Escherichia coli</i> (MDR, ESBL)	BAA-196	15	99.9857
<i>Escherichia coli</i> (O157:H7)	43888	15	99.9967
<i>Haemophilus influenzae</i> (MDR)	33930	15	99.9993
<i>Klebsiella pneumoniae</i> Subsp. ozaenae	11296	15	99.9548
<i>Klebsiella pneumoniae</i> Subsp. pneumoniae	13883	15	99.9880
<i>Lactobacillus plantarum</i>	14917	15	99.9956
<i>Listeria monocytogenes</i>	7644	15	99.9950
<i>Micrococcus luteus</i>	7468	15	99.9978
<i>Proteus hauseri</i> (formerly <i>P. vulgaris</i> )	13315	15	99.9924

<i>Proteus mirabilis</i>	7002	15	99.9852
<i>Proteus mirabilis</i> (ESBL)	BAA-856	15	99.9903
<i>Pseudomonas aeruginosa</i>	15442	15	99.9899
<i>Pseudomonas aeruginosa</i>	27853	15	99.9865
<i>Salmonella enterica</i> <i>enterica</i> serovar Choleraesuis	10708	15	99.9952
<i>Salmonella enterica</i> <i>enterica</i> serovar Enteritidis	13076	15	99.9943
<i>Salmonella enterica</i> <i>enterica</i> serovar Typhimurium	14028	15	99.9929
<i>Serratia marcescens</i>	14756	15	99.8781
<i>Shigella dysenteriae</i>	13313	15	99.9928
<i>Shigella sonnei</i>	11060	15	99.9962
<i>Staphylococcus aureus</i>	6538	15	99.9926
<i>Staphylococcus aureus</i>	29213	15	99.6453
<i>Staphylococcus aureus</i> (MRSA; GRSA)	33593	15	99.9946
<i>Staphylococcus aureus</i> (MRSA; hetero-VISA)	700698	15	99.9836
<i>Staphylococcus epidermidis</i>	12228	15	99.8233
<i>Staphylococcus haemolyticus</i>	43253	15	97.0791
<i>Streptococcus pneumoniae</i>	33400	15	99.9951
<i>Streptococcus pyogenes</i>	19615	15	99.9946
<b>Yeasts and Fungi</b>	<b>ATCC No.</b>	<b>Exposure (seconds)</b>	<b>Percent Reduction</b>
<i>Candida albicans</i>	14053	15	99.7415
<i>Candida tropicalis</i>	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*

# Glove Compatibility

<b>TEST METHOD:</b>	<b>ASTM D5151-99</b>
<b>Purpose of Study:</b>	<b>Determine the effect of product on Medical Gloves including latex, vinyl and nitrile gloves. 300 control gloves and 300 gloves were tested with GOJO® Antibacterial Foam Soap</b>
<b>Testing Lab:</b>	<b>Smithers Scientific Services, Inc.</b>
<b>Date:</b>	<b>21 August 2006</b>
<b>Sample Size:</b>	<b>100 control gloves and 100 gloves were tested with GOJO Antibacterial Foam Soap on 100 each of three glove types. Tested were Latex, Vinyl and Nitrile gloves.</b>
<b>Results:</b>	<b>There were no leaks in the 300 control gloves and there were no leaks in the 100 latex test gloves that had been exposed to the test product. There were two gloves detected with leaks in the nitrile gloves and one glove detected with a leak in the vinyl gloves.</b>
<b>Conclusions:</b>	<b>The test product is compatible with latex, nitrile and vinyl gloves.</b>