

TECHNICAL REPORT

 $\underline{\text{DESCRIPTION}} \text{ - LYSOL? BRAND I.C.? ANTIMICROBIAL SOAP is a healthcare personal handwash formulated to help reduce the risk of cross infection by providing broad-spectrum reduction of pathogenic microorganisms.}$

NDC #00957-310-17 NDC #00957-310-01



DIRECTIONS FOR USE:

Wet hands with water. Add soap and vigorously rub together all surfaces of lathered hands for at least 10 seconds. Thoroughly rinse under a stream of water. Dry thoroughly.

SAFETY REMINDER: Before employees use this or any other product, make sure they read and understand the product label, Material Safety Data Sheet and facility cleaning / disinfection protocol.

PRODUCT USAGE

LYSOL® Brand I.C.™ Antimicrobial Soap is a fast-acting, broad-spectrum antimicrobial healthcare personal handwash. LYSOL® Brand I.C.™ Antimicrobial Soap's mild, non-drying formula helps improve compliance with healthcare protocols that require frequent handwashing. The Centers for Disease Control and Prevention (CDC) guidelines for handwashing indicate that handwashing is required under the following circumstances:

- 1) Before taking care of patients susceptible to infections;
- 2) Before and after touching wounds;
- 3) After situations in which contamination is likely to occur;
- 4) After touching objects that are likely to be contaminated.

SUGGESTED AREAS OF APPLICATION FOR LYSOL® I.C.™ ANTIMICROBIAL SOAP:

Recommended for use in healthcare facilities and commercial settings such as Hospitals, Nursing Homes, Medical Offices, Clinics, Dental Offices, Day Care Centers and Laboratories. LYSOL® Brand I.C.™ Antimicrobial Soap is ideal in situations where hands are washed frequently, as in healthcare settings, and for general use in public areas.

MICROBIOLOGY DATA

Mechanism of Action for Disinfectant Antimicrobial Agents

Generally, disinfectants destroy bacteria by attacking the cytoplasmic membranes or the cellular cytoplasm itself. The action of an antimicrobial agent on a bacterial cell involves first adsorption to the cell surfaces, then penetration of the outer membrane to reach these target sites.

All bacteria contain a cell wall that is unique to this group of organisms. The cell wall gives the cell its shape and rigidity. It is composed of peptidoglycan which is a polymer consisting of a disaccharide repeating unit of two different N-acetylated amino sugars, one of which is attached to a short peptide chain. Individual glycan strands are cross-linked through peptide bonds between the peptide chains. Gram-negative bacteria contain an cytoplasmic membrane consisting lipopolysaccharide (LPS) molecules that surround the cell wall. The outer membrane is unique to Gram-negative bacteria. In addition, these organisms have an inner cytoplasmic membrane on the inside of the cell wall, which is in contact with the cytoplasm. It consists of phospholipids and proteins. The cytoplasmic membrane serves as the selective permeability barrier between the cytoplasm and the cell environment. It is the site at which many of the important cellular functions occur and the target site for many antimicrobial agents. Gram-positive bacteria do not have an outer membrane, only the inner membrane.

Triclosan is a broad-spectrum antimicrobial agent used in deodorant soaps, underarm deodorants, liquid antimicrobial soaps, healthcare personal handwashes and surgical scrubs. Triclosan prevents the uptake of essential amino acids at bacteriostatic concentrations. Bactericidal concentration causes disorganization of the cytoplasmic membrane and leakages of low molecular weight cellular contents.

GERMICIDAL ACTIVITY

Test Method: Evaluation of the Healthcare Personal Handwash – A basis Method

The expected result from using this type of product is the reduction of transient flora acquired as a result of patient care or as a part of hospital routine; therefore, the testing involved simulation of this acquisition by the artificial contamination of the subject's hands. This procedure was executed by spreading a known amount of the inoculum on the hands and allowing one minute to elapse prior to each washing.

Test Conditions: Thirteen subjects were enrolled in the study. Healthcare personal handwashes are designed to be used many times a day by hospital staff; therefore, the effectiveness testing procedure involved repeated hand contamination and washing. The procedure was done 25 times in succession. A minimum of five minutes was allowed between repeats. Microbiological evaluation of the count on the hands was done after the first, fifth, tenth, fifteenth, twentieth and twenty-fifth washes.

The microporous filter technique is a well-established procedure for isolation of microorganisms and this method was issued to recover the viable fraction removed from the hands in the wash water. It was used with the specifications described in the testing guidelines for the testing of healthcare personal handwashing products.

In order to carry out this test reliably, a marker strain of an organism that is not part of the normal skin flora was used. This organism, *Serratia marcescens*, produces a unique growth pattern and color on the recovery medium.

Test Results: Average recovery of S.

marcescens after washing with Lysol® Brand I.C.™ Antimicrobial

Soap (13 subjects)

Organisms	Count	Percent Reduction
Baseline	7.7 x 10 ⁵	Not Applicable
Wash #1	3.5 x 10 ⁵	54.54%
Wash #5	6.3 x 10 ³	99.18%
Wash #10	3.4 x 10 ³	99.56%
Wash #15	4.8 x 10 ³	99.38%
Wash #20	5.5 x 10 ³	99.29%
Wash #25	4.0 x 10 ³	99.48%

MINIMUM INHIBITORY CONCENTRATION (MIC)

Test Method: An in vitro assay that tests against a broad-spectrum of Gram-positive and Gram-negative bacteria and fungi.

This test determines the minimum concentration necessary for the antimicrobial agent to inhibit bacterial growth. The determination is made by incorporating various concentrations of the antimicrobial agent into a culture medium containing the test organism. The treated media are then incubated for a period of time, usually 24 hours. If the antimicrobial agent concentration is too low, growth will be detected in the media. A clear vessel is negative, indicating that the concentration of the antimicrobial agent was great enough to prevent bacterial growth. The last negative dilution in the series of concentrations is the Minimum Inhibitory Concentration (MIC) or lowest concentration of the antimicrobial agent that inhibits growth of the test organism.

Test Conditions: LYSOL® Brand I.C.™ Antimicrobial Soap was tested for MIC against stock culture and clinical isolates of Gram-positive and Gram-negative bacteria and fungi. The antimicrobial agent was twofold serially diluted in a growth broth media. Each tube was then inoculated with the test organism and incubated for 24-48 hours at the appropriate test conditions. After incubation, tubes were examined for signs of growth as determined by a metabolic indicator incorporated into the growth media.

Test Results:

Organisms	ATCC #	MIC Valves
Methicillin Resistant	ATOU #	WIIC Valves
Staphylococcus aureus (MRSA)	33592	>1:1024
Acinetobacter calcoaceticus	15743	1:1024
Candida albicans	10231	1:512
Enterobacter aerogenes	13048	>1:1024
Enterococcus faecalis	828	1:16
Enterococcus faecium	6569	1:10
Escherichia coli	11229	>1:1024
Klebsiella pneumoniae	9997	>1:1024
Listeria monocytogenes	7644	1:512
Micrococcus luteus	7468	>1:1024
Proteus mirabilis	25933	
		>1:1024
Pseudomonas aeruginosa	15442	1:8
Pseudomonas cepacia	35254	>1:1024
Salmonella choleraesuis	10708	>1:1024
Serratia marcescens	14756	1:8
Shigella dysenteriae	11835	1:256
Staphylococcus aureus	6538	>1:1024
Staphylococcus epidermidis	12228	>1:1024
Staphylococcus haemolyticus	29970	>1:1024
Staphylococcus hominis	29885	>1:1024
Staphylococcus saprophyticus	15305	>1:1024
Streptococcus pyogenes	12384	1:16

Clinical Isolates	Site	Inoculum	MIC
		/ML	Valves
Methicillin Resistant			
Staphylococcus	Foot	1/20 x 10 ⁶	1:32
aureus (MRSA)			
Acinetobacter			
baumanni	Sputum	1.21 x 10 ⁶	>1:1024
Candida albicans	Sputum	5.96 x 10 ⁶	1:512
Enterobacter			
aerogenes	Left Hip	1.26 x 10 ⁶	>1:1024
Enterococcus faecalis	Right Foot	1.57 x 10 ⁶	1:8
Klebsiella pneumoniae	Urine	3.04 x 10 ⁶	>1:1024
Proteus mirabilis	Urine	1.74 x 10 ⁶	>1:1024
Pseudomonas			
aeruginosa	Urine	9.70 x 10 ⁵	1:8
Serratia marcescens	Urine	1.10 x 10 ⁶	1:16
Staphylococcus			
aureus	Wound	1.58 x 10 ⁶	1:16
Staphylococcus			
epidermidis	Wound	3.70 x 10 ⁵	1:32
Staphylococcus			
haemolyticus	Bone/Heel	3.03 x 10 ⁶	1:16
Staphylococcus			
saprophyticus	Urine	1.10 x 10 ⁶	>1:1024
Streptococcus			
pyogenes	Urine	1.43 x 10 ⁶	>1:1024

PHYSICAL DATA

CHARACTERISTIC	PHYSICAL PROPERTY / TEST RESULT
Appearance	Pearlescent white lotion
Odor	Light Floral
рН	6.2 – 7.2
Density / Specific Gravity @ 25°C	1.02
Viscosity	3,000-6,000 cps
Flash Point	>200°F
Shelf Life	2 years
Stability (Freeze/Thaw)	Stable

OTHER INFORMATION

N.F.P.A. Hazard Rating

Health	0	Negligible
Fire	0	Negligible
Reactivity	0	Negligible

H.M.I.S. Hazard Rating

Health	0	Minimal
Flammability	0	Minimal
Reactivity	0	Minimal

N.F.P.A. – National Fire Protection Agency N.M.I.S. – Hazardous Material Identification System

PRECAUTIONARY STATEMENTS:

KEEP OUT OF REACH OF CHILDREN

WARNING: Avoid contact with eyes. In case of eye contact, immediately flush eyes thoroughly with water, remove

any contact lenses, and continue to flush eyes with plenty of water for at least 15 minutes. Do not use

this product on infants under 6 months of age. For external use only.

STORAGE: Store in areas inaccessible to children.

Satisfaction Guaranteed: Careful laboratory control assures materials of uniform quality at all times. All Reckitt Benckiser Professional products are guaranteed to give complete satisfaction, when used as directed, or they may be returned for credit.

LYSOL® Brand I.C.™ Antimicrobial Soap is part of a system of infection control products provided by Reckitt Benckiser Professional.

QUESTIONS? COMMENTS? CALL 1-800-677-9218

VISIT US AT: www.reckittprofessional.com

DISTRIBUTED BY:

RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE, NEW JERSEY 07474-0977

PACKAGING DESCRIPTION LYSOL® Brand I.C.™ Antimicrobial Soap		
ORDER NO.	SIZE	CASE CUBE
36241-95717	17.5 oz. Plastic Bottles 12 per case	0.59
36241-95701	1 Gallon Plastic Bottle 4 per case	1.12

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