Research Bulletin

Discovery Medical, Inc.

No-Rinse

Discovery Medical, Inc.
Anaheim, CA 92805 USA

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The Role of Alcohol /Parachlorometaxylenol (PCMX) as an Antiseptic Agent

Discovery Non-Flammable Hand Sanitizer™ provides its antimicrobial activity due to the synergistic activity of two distinct active ingredients; Alcohol and PCMX. Alcohol is classified by the United States Food and Drug Administration (FDA) as a monograph level I agent which is the highest level of antimicrobial classification granted by the FDA. This designation means that alcohol has undergone close scrutiny and extensive testing to prove its effectiveness as an antimicrobial agent. PCMX exhibits both cidal and static activity and together they provide a high level of efficacy against a broad range of microorganisms.

By breaking the chain of cross contamination, this alcohol/ PCMX formulation has demonstrated itself to be an effective agent with rapid kill times against a broad range of gram negative and gram positive bacteria, fungi, as well as some viruses. A combination of 10% alcohol and 0.5% PCMX meets the standards for classification as an antiseptic and is so registered with the FDA under NDC #63631-105.

When used as directed, this mixture is safe and effective, and typically does not produce clinically significant irritation or sensitization problems.

Healthcare Personnel Antiseptic Hand Rinse Studies

Objective

A technique was used to determine the percent of reduction in transient bacteria on subjects' hands and forearms.

Methodology

First, a baseline bacterial count was determined for each subject by contaminating the subjects' hands with Serratia marcescens or Bacillus subtilis var.niger (globigii) and having the subjects rub the culture over both hands and forearms. After the baseline determinations were completed, each subject repeated the contamination with Serratia marcescens or Bacillus subtilis var.niger. The subjects then performed a waterless hand rinse for a 15 second period of time with the antiseptic hand gel. This process was carried out for 25 consecutive times. Microbial reduction was measured after the 1st, 4th, 7th and 10th hand rinses and was compared to the baseline count. The 11th through the 25th hand rinses are performed to assess irritancy potential.

Results

Waterless Hand Rinse Study

	1st wash		4th wash		7th wash		10th wash	
Product	**Log_{10}**	**Percent**	**Log_{10}**	**Percent**	**Log_{10}**	**Percent**	**Log_{10}**	**Percent**
gel	2.603	99.75	2.696	99.8	2.775	99.83	3.115	99.92

Conclusion

Tests demonstrate that the antiseptic hand gel delivers greater than 99.92% reduction in transient bacterial count when being used as a healthcare personnel antiseptic hand rinse. No adverse irritancy was noted from repeated use throughout this study

Microbial Kill Time Studies

Objective

This test was designed to evaluate the bactericidal activity against a broad range of both gram negative and gram positive bacteria as well as fungi.

Test Microorganisms

The efficiency to demonstrate bactericidal activity was evaluated by using a standardized suspension of each of the following test organisms:

Canadida albicans	ATCC #10231	Staphylococcus aureus	ATCC #6538
Streptococcus faecalis	ATCC #6569	Escherichia coli	ATCC #8739
Pseudomonas aeruginosa	ATCC #15442		

Methodolgy

The efficacy of the test material to demonstrate cidal activity was evaluated following a modification of the Antimicrobial Preservatives Effectiveness Test, described in the United States Pharmacopeia XXI, 1985, Section 51. The procedure was modified by utilizing additional test microorganisms (Salmonella, Serratia, Listeria) and adding additional assay periods of 15 seconds, 30 seconds and 60 seconds post inoculation.

Following determinations of initial microbial load, the test material was inoculated with suspensions of the test organisms. At post inoculation intervals of 30 and 60 seconds, 7 days, 14 days, 21 days and 28 days; microbial populations were determined using standard plating procedures.

Results

(CT/gm Product % Reduction)

Organism	ATCC Strain	30 sec	60 sec	7 days	14 days	21 days	28 days	Inoculum
P. aeruginosa	9027	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$5.1x10^6$
S. aureus	6538	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$7.6x10^6$
S. marcescens	13880	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$5.3x10^7$
S. typhi	6539	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$1.6x10^7$
L. monocytogenes	15313	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$1.1x10^7$
E. coli	8739	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$1.5x10^7$
C. albicans	10231	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$5.7x10^5$
A. niger	16404	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	$1.6x10^5$

Conclusion

Test results demonstrate a rapid kill time on gram-positive and gram-negative bacteria as well as fungi, with no re-growth occurring over a 28 day test. .

Antibiotic-Resistant Organisms Kill Time Studies

Objective

This test was designed to evaluate the antimicrobial effectiveness against the antibiotic-resistant organisms Vancomycin-Resistant Enterococcus faecium (VRE) and Methicillin-Resistant Staphylococcus Aureus (MRSA).

Test Microorganisms

Standardized suspensions of the following microorganisms were used to conduct this study:

Enterococcus faecium (VRE)	ATCC #51559
Staphylococcus aureus (MRSA)	ATCC #33591

Methodology

Bactericidal activity was determined by inoculating each test microorganism suspension into a 20.0g aliquot of the test material. At post inoculation times of 0 seconds (immediately after inoculation), 15, 30 and 60 seconds; surviving populations were determined. Enumerations were conducted using standard plating procedures using soybean casein digest agar with letheen.

Results

Average Counts Per ML (log_{10})

Exposure Time	E. faecium (VRE)	S. aureus(MRSA)
0 seconds	1.7782	4.2553
15 seconds	≤1.0000	1.301
30 seconds	≤1.0000	≤1.0000
60 seconds	≤1.0000	≤1.0000
inoculum	6.5911	6.699

Percent Reductions

Exposure Time	E. faecium (VRE)	S. aureus(MRSA)
0 seconds	≥99.99	99.82
15 seconds	≥99.99	≥99.99
30 seconds	≥99.99	≥99.99
60 seconds	≥99.99	≥99.99

Conclusion

Test results demonstrate a rapid kill time on antibiotic-resistant organisms such as Vancomycin-Resisant Enterococcus faecium (VRE) and Methicillin-Resistant Staphylococcus Aureus (MRSA)..

Toxicity Studies

Acute Toxicity Testing
Project ID NVP Report No. X8B113G

Study	Result
Acute Oral Toxicity	An oral dose of 5 g/kg produced no mortalities
Acute Dermal Toxicity	A dose of 2 g/kg produced no mortalities
Primary Skin Irritation	Non-irritating
Primary Eye Irritation	Produces some moderate, temporary eye irritation*

Conclusion: This product is non-toxic upon oral ingestion at the dose stated above. It is non-toxic upon skin contact, non-irritating as a primary skin irritant, and is a moderate, but temporary primary eye irritant.

*Slight conjunctivitis with discharge cleared after seven (7) days.