

ABSTRACT

Background: Nosocomial infections are a serious problem in healthcare facilities and poor hand hygiene has been determined to be a major factor in causing and spreading such infections. It has been determined that proper hand washing with an appropriate antimicrobial soap can significantly reduce the risk of infection. The current antimicrobial hand sanitizers are mainly based on alcohol, parachloro-meta-xyleneol (PCMX), chlorohexidine and Triclosan. These chemicals have shown limitations when applied on hands, notably short-term tolerability and/or efficacy. This is due to the fact that it is difficult to formulate the necessary balance between their microbial efficacy and user safety. The objective of this study is to introduce a new handwash antimicrobial solution based on the Accelerated Hydrogen Peroxide (AHP) technology.

Methods: European test methods have been used to evaluate the efficacy and skin sensitivity of the handwash antimicrobial solution.

Results: The product inactivates different bacteria and does not irritate skin upon extended exposure.

Conclusions: This new product addresses many of the concerns associated with the legacy handwash products.

INTRODUCTION

Hospital-acquired infections affect up to 10% of hospitalized patients per year, and are the direct or indirect cause of 88,000 deaths. Handwashing is one of the most important measures for reducing transmission of nosocomial infections in health care facilities. Currently alcohol based formulations are the most commonly used products for hand sanitation. Although alcohols have good antimicrobial activity, there is growing concern over their safety, particularly flammability. Moreover, alcohols are known to dry hands when used repeatedly.

MATERIALS AND METHODS

Formulation tested: The product tested in this study, Flora Free, is a newly developed, AHP-based hand sanitizer.

Flora Free is a blend of 3% hydrogen peroxide, stabilizers, emollients and surfactants. It is a clear, colorless, odorless liquid with a pH of 3.0 to 4.0. It is free from alkyl phenol ethoxylates (APEs) and Volatile Organic Compounds (VOC). The formulation is in the registration process for sale in Canada, however is now used throughout Europe.

Flora Free has been tested for antimicrobial activity, toxicity, irritation and stability using well-recognized and accepted European protocols.

Stability Tests were done to comply with paragraph C.01.062 in the Food and Drugs Act, wherein the concentration of medicinal active in a drug product cannot lie outside of a band defined by 90% to 110% of the nominal concentration.

Antimicrobial Tests were done using the European in-vivo and in-vitro norms.

Irritation Tests were done using the European standards.

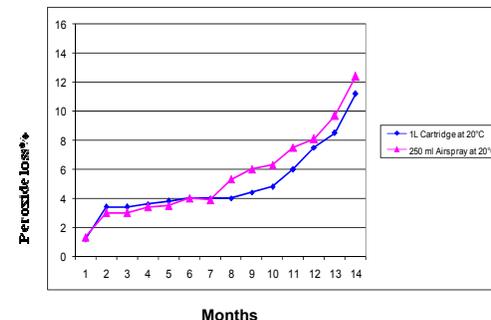
Toxicological evaluation was performed using CAS numbers and chemical names of ingredients.

RESULTS

Antimicrobial tests

EN 1499	In vivo Bactericidal test Log reduction: product is significantly better than the reference soap	➤ <i>Escherichia coli</i> K12 NCTC
Pr EN 12054	In vitro Bactericidal test Interfering substance = hard water at 300 mg/kg CaCO ₃ . Log ₁₀ reduction: 3	➤ <i>Pseudomonas aeruginosa</i> ATCC 15442 ➤ <i>Escherichia coli</i> CIP 54.117 ➤ <i>Staphylococcus aureus</i> ATCC 6538 ➤ <i>Enterococcus hirae</i> ATCC 10541
EN 1276	In vitro Bactericidal test Interfering substance = hard water at 300 mg/kg CaCO ₃ . Log ₁₀ reduction: 5	➤ <i>Pseudomonas aeruginosa</i> ATCC 15442 ➤ <i>Escherichia coli</i> ATCC 10536 ➤ <i>Staphylococcus aureus</i> ATCC 6538 ➤ <i>Enterococcus hirae</i> ATCC 10541
EN 1040	In vitro Bactericidal test Interfering substance = none Log ₁₀ reduction: 5	➤ <i>Staphylococcus aureus</i> MRSA CIP 107.397 (Methicillin-resistant) ➤ <i>Enterobacter aerogenes</i> BLSE CIP 105.091 (β-lactam, aminoglycosid, fluoroquinolon and imipenem-resistant) ➤ <i>Salmonella enterica</i> CIP 58.58 ➤ <i>Listeria monocytogenes</i> CIP 105.458
EN 1275	In vitro Fungicidal test Interfering substance = none Log ₁₀ reduction: 4	➤ <i>Candida albicans</i> ATCC 10231 ➤ <i>Aspergillus niger</i> ATCC 16404

Stability Tests results at room temperature for 1 L cartridge and 250 ml packages:



Toxicological and skin irritation test results:

Toxicological approval: Done by a toxicologist on the base of CAS numbers and chemical names of ingredients Prof. A. Botta, Faculté de Médecine. 13385 Marseille - FRANCE	The product has no potential systemic toxicity
Skin irritation test: In vivo 48h single patch-test done on a minimum of 10 subjects. Laboratoire IDEA - 33651 Martillac - FRANCE	The product at pH 3 is classified as non irritant
Dermatological test: In vivo usage-test done on a minimum 20 subjects and validated by a dermatologist. Sequani - ENGLAND	The product is dermatologically tested
After-washing skin hydration In vivo measurement of Trans Epidermal Loss (TEWL) done on a panel of 9 subjects during 5 days Deb Ltd - Belper - ENGLAND	<p>The product does not induce skin dryness</p>

DISCUSSIONS AND CONCLUDING REMARKS

It is very important for an antimicrobial hand wash to have a fair balance between its microbial activity, safety and skin mildness. Although legacy products lack this balance, Flora Free has both high antimicrobial activity, product safety and low skin irritation. Therefore, it addresses the core disadvantages of the current products such as alcohol, chlorohexidine, Triclosan and PCMX.