WHITE PAPER

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Alcohol Based Hand Rubs –effective formulations are key for reducing the risk of Healthcare Associated Infections for patients and adoption by healthcare staff, but how to choose the right product for your healthcare facility?

INTRODUCTION

This paper details key considerations for choosing a suitable alcohol based handrub (ABHR) for healthcare facilities and how making the right choice can lead to greater adoption for healthcare staff, resulting in increased compliance in hand hygiene and reduced risk of associated infections for patients. Firstly, there is a big challenge in interpreting the wealth of information available from national and international guidance, existing scientific evidence, regulations and communications via mainstream media, whilst also considering feedback from healthcare professionals on personal preference.

This paper addresses the key attributes that are needed for an effective ABHR for healthcare facilities and provides a solution as to how to choose products that meet requirements for widespread adoption. These include ingredients that deliver a formulation that performs in all areas – efficacy, skin friendliness, ease of use and tolerability for healthcare staff.

Confidence in industry partners who manufacture such products is also important to ensure healthcare facilities can have assurance in quality of products, supported by strong quality, scientific and regulatory support.

BACKGROUND

ABHRs have been well established in healthcare settings across the world following the research published by Prof. Didier Pitter at the Geneva University Hospitals[1] and the subsequent publication of the WHO Guidelines on Hand Hygiene in Healthcare in 2009[2]. There is a variety of ABHR products available in the market for use in healthcare. These products are marketed with claims of high-quality formulations, rapid microbial efficacy, skin friendliness and ease of use. The key to adoption of these products is how well these features are balanced, which can aid compliance in use.

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HOW TO CHOOSE ABHR THAT IS RIGHT FOR HEALTHCARE

Efficacy requirements for hand hygiene in healthcare depend on application. In public and clinical areas, such as patient wards & single rooms, examination rooms and outpatient clinics, hygienic hand disinfection products are needed. These products need to be effective against transient microorganisms that are picked up by hands and are 'resting' temporarily on the surface of the skin and can be transmitted to patients, equipment and environment easily. For surgical hand antisepsis, the aim is to reduce microorganisms, both transient and resident which lie deeper in skin layers from both hands and arms, before donning surgical gowns and gloves. Demonstrating efficacy for both hygienic and surgical applications can be achieved using specific European Normative (EN) tests.

In addition to the ability to reduce the number of microorganisms to a safe level achieved by hygienic & surgical disinfection, products also need to be skin friendly and acceptable to staff in order to ensure compliance in use for all clinical situations where hands need to be 'clean'.

There are many factors that aid compliance, such as education & training, reminders on importance of hand hygiene and a culture of high standards of compliance in facilities, but where products are concerned, ease of use, user acceptability and skin friendliness are key. Therefore, a product formulation balancing these elements with efficacy is the way to achieve the goal of high compliance.

EFFICACY OF ALCOHOL BASED HANDRUBS

As hand hygiene is recognised as the single most effective intervention for reducing the risk of transmission of hospital associated infections (HAIs), suitable antimicrobial efficacy must sit at the top of the priority list, when choosing a product.

Regulations that apply to ABHRs sold in the EU such as Biocide Product Regulations (BPR) and Medicinal Regulations Directive 2001/83/EC relating to medicinal products for human use determine required standards for efficacy.

For biocidal products, guidance from the European Chemical Agency (ECHA) on BPR on the required efficacy for biocidal products detail the minimum requirements[3]. As a minimum, bactericidal and yeasticidal efficacy is required and with an option to pursue additional claims relevant for application area, with mycobactericidal and virucidal efficacy also being relevant for healthcare.

For Medicinal Products, which are supported by a complex dossier to ensure the appropriate quality, safety and efficacy, according to the European Standards are laid down in EU Directive 2001/83/EC relating to medicinal products for human use. Data included in such dossiers is evaluated by the competent national authority to get the marketing authorization granted.

Demonstration of efficacy is carried out according to the European Normative (EN) tests. The below table illustrates required tests for both hygienic and surgical handrubs, as determined by EN 14885: 2018 Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics[4]

	Hygienic Hand rub	Surgical Hand rub
Bactericidal	EN 13727*	
	EN 1500**	EN12791**
Yeasticidal	EN 13624*	
Mycobactericidal	EN 14348*	
Virucidal	EN 14476*	

*Phase 2, Step 1 suspension test; **Phase 2, step 2 practical test

FORMULATION OF ABHR PRODUCTS AIDS EFFICACY

In order to meet the requirements of EN efficacy tests, products are formulated with high levels of alcohol (60-90% w/w) and other ingredients that ensure the alcohol has maximum biocidal effect, spread easily on skin, in addition to moisturising and skin protection properties to ensure products are well tolerated. ABHR formulations based on ethanol provide superior efficacy, specifically against viruses, when compared to 1-isopropanol, 2-isopropanol and blended isopropanol formulations. This efficacy was demonstrated in a comparable study of efficacy of different alcohols against murine Norovirus[5]. The alcohol content of ABHR is the primary ingredient that determines efficacy, due to its ability to inactivate bacteria by denaturing proteins and breaking down cell membranes and inactivating viruses. However, it is the complete formulation, combining the alcohol content and other ingredients, which is responsible for how effective a product is against microorganisms.

It is well understood that there is an alcohol concentration range that is considered optimal for efficacy. The recommendations provided in ‘Hand Hygiene; A handbook for Medical Professionals[6], published in 2017 and edited by Didier Pittet, provides updated evidence and guidance. Chapter 8, titled ‘Hand Hygiene Agents’, states ‘solutions containing 60-95% alcohol are effective’. Concentrations of 70% w/w and above alcohol are needed to ensure non- enveloped virucidal efficacy, especially against Norovirus and Rotavirus, which are critical for Healthcare. This range is also considered to be optimal, as the additional water content is required to denature proteins and permeate cell membranes.

An important consideration in stating percentages of alcohol content is that the detail often missed is the fact that alcohol content may be expressed as percent by weight (w/w), which is not affected by temperature or other variables, or as percent by volume (v/v), which can be affected by temperature, specific gravity, and reaction concentration. For example, an ABHR with alcohol content listed as 70% (v/v) when converted to (w/w), the content is 62.4% (w/w), thus demonstrating the importance of including this detail.

Concentration of ethanol by weight (w/w)	Concentration of ethanol by volume (v/v)
52.1%	60.0%
54.1%	62.0%
60.0%	67.7%
61.0%	68.7%
62.4%	70.0%
65.0%	72.4%
70.0%	77.0%
73.5%	80.0%
75.0%	81.3%
80.0%	85.5%
85.0%	89.5%
89.0%	92.5%
90.0%	93.3%
95.0%	96.8%

Reference: European Pharmacopoeia 7.0, 2011.

MANUFACTURE AND QUALITY OF ABHR PRODUCTS

The manufacture of ABHR products is important in terms of quality of final products delivered to customers. Manufacturing plants working to Good Manufacturing Practice (GMP) ensure quality of the facility and manufacturing process, along with quality control and are described within documented Quality Assurance systems. Raw materials and final products undergo strict quality control, with specifications on quality & quantity of key ingredients.

SOLUTION: SKINMAN© SOFT PROTECT & SKINMAN© SOFT PROTECT FF

Skinman© Soft Protect & Skinman© Soft Protect FF (fragrance free) are liquid ABHRs designed for frequent use across all healthcare facilities & departments without comprising efficacy. A liquid formulation that is easily spread on hands, ensuring coverage with a contact time of 30 and 90 seconds for hygienic and surgical hand disinfection respectively. It is effective against bacteria, yeasts & viruses. Combined with 89% w/w ethanol, key skin friendly ingredients such as Vitamin E, glycerine and panthenol deliver essential skin protection, moisturising and skin regeneration properties. The formulations for Skinman© Soft Protect and Skinman© Soft Protect FF are identical, with exception of the fragrance.

Skinman© Soft Protect is the only formulation to have been successfully assessed by healthcare workers in a hospital setting using a WHO protocol for skin tolerability & acceptability[7] by Professor Sax and his team at Universitäts Spital Zürich. **Skinman© Soft Protect** was assessed by an independent trained observer using a validated scale to provide an objective assessment of skin condition, examining criteria such as redness, scaliness, dry skin and irritation, appearance, moisture content and overall skin integrity over a period of 30 days. Participants scored the product very highly in all aspects of skin tolerability, as shown in the figure below. Significantly, participants scored overall integrity of their skin as 74.9% at baseline, increasing to 88.8% after 3 months of using **Skinman© Soft Protect.**

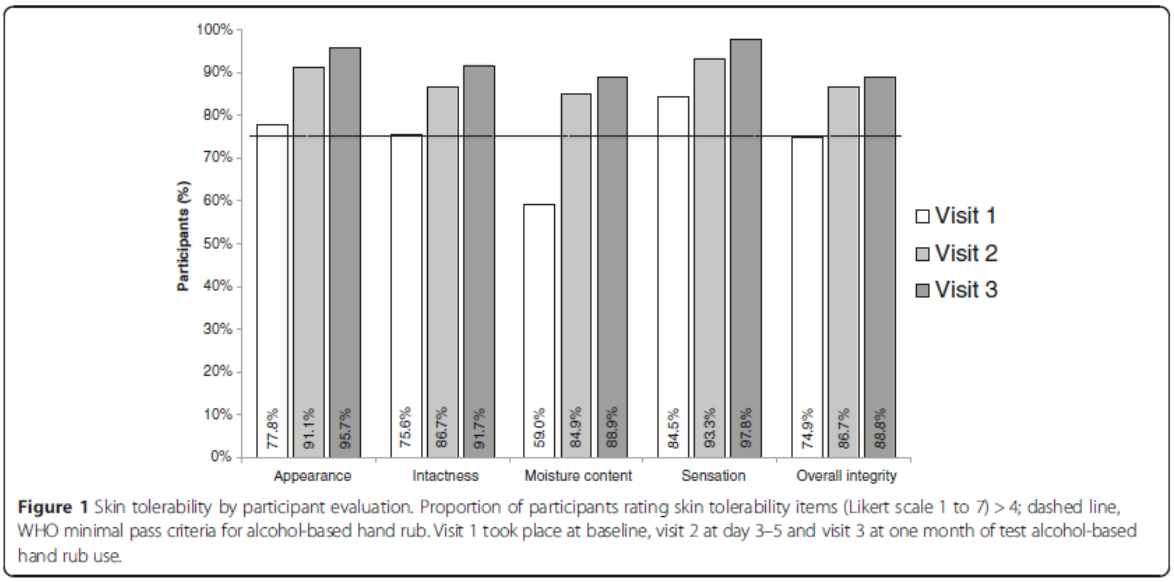

Figure 1 Skin tolerability by participant evaluation. Proportion of participants rating skin tolerability items (Likert scale 1 to 7) > 4; dashed line, WHO minimal pass criteria for alcohol-based hand rub. Visit 1 took place at baseline, visit 2 at day 3–5 and visit 3 at one month of test alcohol-based hand rub use.

Efficacy of **Skinman© Soft Protect** & **Skinman© Soft Protect FF** was assessed using both EN 1500 and EN 12791 test methods, where the product is tested for efficacy for use as hygienic and surgical hand antisepsis. Other EN test methods for efficacy against different microbes, such as bacteria, yeasts and viruses (EN 13727, EN 13624 & EN 14476) provide evidence of a rapid, broad spectrum efficacy for all pathogenic microbes relevant for Healthcare. **Skinman© Soft Protect & Skinman© Soft Protect FF** therefore offer a rapid disinfection for surgical hand antisepsis in 90 seconds, when compared to traditional scrubs, which require 3-5 minutes, with additional time for drying hands and arms.

Skinman© Soft Protect & Skinman© Soft Protect FF are registered biocides in Europe.

WHY CHOOSE ECOLAB?

Ecolab's ABHR products offer rapid kill of a wide variety of clinically relevant pathogens including yeasts, gram-positive and gram-negative bacteria including mycobacteria and viruses, demonstrating broad-spectrum antimicrobial efficacy and test results substantiate the antimicrobial properties of each ABHR, consistent with WHO Guidelines.

The strength & scale of Ecolab serves well to meet the needs of customers, with strong R&D, regulatory and quality expertise, which ensures delivery high quality products. Ecolab is a member of POPS (Private Organisations for Patient Safety) set up by WHO to engage with private industry companies with the aim to harness industry strengths to align and improve implementation of WHO recommendations across the world. The group is focussed on increasing education and awareness on the importance of hand hygiene in healthcare and improving access to commodities such as alcohol-based handrub.

CONCLUSION

In summary, the choice of an alcohol-based hand rub needs to consider efficacy as a key factor and this is determined by the whole formulation, rather than solely the alcohol content. Products should offer skin friendly properties that, when combined active ingredients offer the best solutions for user acceptability and high compliance rates to help reduce healthcare associated infections.

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ECOLAB HEALTHCARE
Richtistrasse 7
8304 Wallisellen
Switzerland

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