Communication by the VAH Disinfectants Commission

On the VAH certification of non-alcohol-based handrubs

Verbund für Angewandte Hygiene e.V.
Desinfektionsmittel-Kommission

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Background

The Disinfectants Commission of the Association of Applied Hygiene (VAH) has recently been receiving an increasing number of applications for certification of hand disinfectants whose effect is not primarily based on alcohols. In the active ingredient composition of these products, alcohol either has a minor role as auxiliary component or no alcohols are contained at all.

It is important to the Disinfectants Commission to emphasize that **alcohol-based disinfectants** with the active substances ethanol, n-propanol and isopropanol with a minimum exposure time of 30 s **continue to represent the gold standard** for hand disinfection [see KRINKO recommendation [1]]. This is the case both with regard to the efficacy of alcohol-based products and with regard to skin compatibility and the lack of tolerance formation, mutagenicity, teratogenicity or carcinogenicity of alcohols [2, 3, 4]. A risk of relapse for alcoholics does not exist [5]. For the selection of hand disinfectants in the medical and nursing sectors, the recommendation of the German Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute from 2016, Section 3.1 [1], may be consulted.

Skin compatibility is a highly relevant factor for the quality of handrubs (hand disinfectants). Although indications for hand disinfection vary, in the healthcare sector an average of 70 to 190 uses per day can be assumed, depending on the work area [6–8]. Since the onset of the SARS-CoV-2 pandemic, hand disinfection has also become much more common in the consumer sector. Skin tolerance tests such as simple epicutaneous tests, which test a single application of the product, cannot provide information about the effects in routine use.

Notes on the regulatory classification of hand disinfectants and the testing of compatibility in humans

Until a few years ago, the vast majority of hand disinfectants on the market in Germany were declared as medicinal drugs. In the process of drug approval, in addition to the proof of efficacy and the evaluation of the purity and quality of the ingredients, not only the active ingredients, but the entire product in its form of application (including all compounds of the formula) are tested for topical compatibility for humans and for tolerability. Handrubs already approved as medicinal drugs may keep this status (Section 2 (4) sentence 1 AMG); they can continue to be marketed as medicinal drugs.

Today, however, hand rubs are usually classified as biocides of **product type 1 (PT1), Human Hygiene**. For example, 2-propanol-containing products intended for hand disinfection, including surgical hand disinfection, are now biocidal products (European Commission Implementing Decision (EU) 2016/904 pursuant to Article 3(3) of Regulation (EU) No 528/2012 (BPR)) (see also [9]).

Biocidal products containing **existing active substances** which benefit from the applicable **transitional provisions** for biocide legislation may currently still be **placed on the market and used in Germany without prior authorization** [10]. They merely have to be **registered** as a biocidal product pursuant to the Biocide Notification Ordinance. For this purpose, they receive a **notification number** (N-XXX) by BAuA and are listed in the BAuA database of notified products (note: *BAuA is the abbreviation for the Federal Institute for Occupational Safety and Health in German*). In order to obtain a BAuA notification number, **product-specific testing of efficacy or skin compatibility is not required**.

The **approval process for biocides** usually **includes** the **assessment of skin compatibility**. The tests for topical compatibility depend on a number of factors. Generally, skin sensitization, skin corrosion as well as skin irritation are assessed. Under certain conditions, these tests may not be required for the product, for example, tests for skin sensitization, if valid data are available on each of the constituents of the mixture of ingredients that allow the mixture to be classified according to the applicable rules and provided that synergistic effects between the constituents are not expected [11].

Against the background of these facts and the importance of skin compatibility for the application of handrubs, the Disinfectants Commission in the VAH decided to impose special additional requirements on the certification of non-alcohol-based hand disinfectants.

Additional requirements for VAH certification of non-alcohol-based hand rubs

Chlorine-based handrubs

Already in its communication of June 2020 [12], the Disinfectants Commission formulated warnings for purchasers and users of chlorine-releasing disinfectants, especially sodium hypochlorite, in connection **with instability and possible skin irritation**. In addition, the Commission announced in its communication in Hygiene&Medizin 10/2020 that products based on electrolytically generated aqueous chlorine solutions for the area of hand disinfection will only be accepted for VAH certification if the products can demonstrate **the approval as drug or as biocide** [13]. An assessment of the skin compatibility in long-term use of chlorine-based hand disinfectants is still not available.

The active ingredients "active chlorine released from hypochlorous acid" and "active chlorine released from sodium hypochlorite" are now approved as active ingredients for PT1 [14]. However, to date (as of May 31, 2021), there is **no biocidal product approved for hand disinfection that contains either one of these active ingredients** [15].

Handrubs based on quaternary ammonium compounds

Quaternary ammonium compounds (QAC) have been added as auxiliary active ingredients to alcohol-based products in small percentages (< 1%) for some time already. This admixture might lead to a more sustained effect (remanence), but an improved efficacy per se has not generally been determined [3]. Again, for the selection of handrubs, please refer to the KRINKO recommendation from 2016 on hand hygiene in healthcare [1]. The detailed information on the certified products in the VAH list online contains the individual active ingredients for each individual product with quantity details.

As of now (May 31, 20221), there is no quaternary ammonium compound which has been approved as active substance for PT1. A final overall evaluation of these compounds, including their skin compatibility, by the European authorities is still pending for PT1. Handrubs based on QAC may still be

marketed and used without PT1 approval under the transitional provisions for existing ingredients. Studies or experience confirming the skin compatibility of QAC as main active substance under the conditions of everyday use of handrubs are not yet available. A study from the USA, which investigated occupational allergic skin diseases in healthcare workers, confirmed an allergen potential (contact dermatitis) for the QAC benzalkonium chloride [16, see also 17, 18].

Based on these facts, the Disinfectants Commission considers it essential to impose **additional** requirements for certification and listing with the VAH for hand disinfectants whose **main** active ingredients are QAC. In analogy to the electrolytically produced aqueous chlorine solutions, the Disinfectants Commission has therefore decided, **for the time being, not to certify any more hand disinfectants whose main active ingredients are quaternary ammonium compounds and which have neither been approved as medicinal drug nor as biocidal products** (and thus also proof of skin compatibility).

For handrubs without drug or biocide approval with QAC as the main active ingredient, which had already submitted an application for certification or recertification to the VAH **before the cut-off date of May 31, 2021**, an exemption was granted. These products will be certified without proof of drug or biocide approval or will retain their certificate until expiry with an additional note on the certificate and in the disinfectant list. The note is removed as soon as the respective product has been approved as a biocide for PT1.

Note on products for hygienic handwash

Products referred to as “Hygienic handwash products” (cf. European Standard EN 1499:2013 or VAH Method 10) are subjected to standardized efficacy testing. Requirements on hygienic handwash products are lower than those on hand disinfectants. Hygienic handwash products do not constitute an alternative to hand disinfectants. VAH only certifies hygienic handwash products which are thoroughly rinsed with water after the rubbing procedure. In the view of the Disinfectants Commission and based on current knowledge, quaternary compounds in these products therefore pose a lower risk for skin sensitization or corrosivity.

Iodine-based handrubs

All iodine-based hand disinfectants currently listed in the VAH Disinfectants List have a drug registration. This registration is published online in the VAH list. Products based on iodine are primarily used as skin antiseptics, for which a drug approval by the BfArM is a prerequisite.

Other active substance groups

The active substance groups guanidine derivatives (e.g. chlorhexidine digluconate), glycol derivatives, pyridine derivatives (octenidine dihydrochloride), hydrogen peroxide, organic acids and phenol derivatives are not included in VAH-certified hand disinfectants as main active substances, **but only as additional active substances**. The situation is different with peracetic acid: it is included once as a main active ingredient.

Conclusion

Hand disinfectants based on alcohols as active substances have proven their worth worldwide for many decades. In addition to their efficacy within very short contact times, they also exhibit good skin compatibility. Hand disinfectants based on quaternary compounds or active chlorine have not yet been assessed during longterm everyday use and have not yet been subjected to a comprehensive formal approval procedure with evaluation of skin compatibility by the European authorities. Such an evaluation is of particular importance for hand disinfectants, since they are used directly on human skin, i.e. living tissue, and sometimes with high frequency.

The Disinfectants Commission in the VAH does not wish to prejudge the biocide approval procedures. With effect from 31 May 2021, hand disinfectants based on non-alcoholic active substances for which sufficient experience in practical use is lacking or not yet available will therefore only be certified by the Disinfectants Commission after completion of the formal approval procedure for PT1, including testing of skin compatibility. This does not apply to alcohol-based products containing non-alcoholic active ingredients as additional active ingredients in small quantities (< 1%) or hand disinfectants that can demonstrate approval as medicinal drugs or biocides.

In order to protect the health of each individual as well as the population as a whole, the Disinfectants Commission in the VAH reserves the right to modify the requirements for certification and listing in order to continue to guarantee the efficacy and safety of the certified products in the event of changes in the general conditions. As a result, the VAH list remains an indispensable reference for the selection of comprehensively evaluated disinfection products.

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