



Verbund für Angewandte Hygiene e.V.

Quality Marks for Purchasing Hand Disinfectants

Background

Purchasing disinfectants is a major challenge, in particular in the current situation in which many new products have been placed on the market. For guidance purposes, the German Association for Applied Hygiene (**VAH**) has therefore compiled a tabular overview of important information on **quality assurance**.

This is intended, on the one hand, for users in medical and nursing institutions and, on the other hand, for users who need effective disinfection products to meet infection protection requirements in the routine occupational setting. These include public institutions and commercial enterprises supervised by the public health service as well as other bodies responsible for the occupational safety of their employees.

When purchasing disinfectants in the time of the COVID-19 pandemic, based on **risk assessment** it must first of all be ascertained which disinfectant **spectrum of action** is required. As a general rule, the minimum prerequisite for any disinfectant is efficacy against bacteria, yeasts and enveloped viruses.

Currently, there are no plans to test specifically for efficacy against the SARS-CoV-2 virus, the causative agent of COVID-19 disease. However, based on the current state of knowledge the healthcare authorities and scientists in Germany and throughout Europe are unanimous that a "**limited virucidal**" (**active against enveloped viruses**) or alternatively, "**limited virucidal PLUS**" (enveloped viruses plus Adenovirus, Rotavirus, Norovirus), or "**virucidal**" **spectrum of action also includes inactivation of the SARS-CoV-2 virus** (please refer to the information available on the website of the Robert Koch Institute [RKI]).

In this first overview we focus on the quality marks for hand disinfection. Non-medical institutions, in particular, must check in each case whether hand washing suffices as a hand hygiene measure.

A disinfectant product is beneficial only when properly applied. Training or induction to that effect by qualified personnel is advisable. In the medical setting professional training is a prerequisite for use in all cases.

Hand disinfection must be carried out while ensuring that all areas of the hand are thoroughly wetted with the disinfectant solution. As a general rule, hand disinfection is performed with a 3 ml volume (depending on the size and condition of the hands) and a contact time of 30 s, while always observing the manufacturer's instructions. The hands must not be rinsed off afterwards!

Likewise, for hand washing it must be ensured that soap is applied thoroughly, but gently, to all areas of the hand while creating a lather; it is also important to ensure that the hands are thoroughly rinsed and dried.

It is not possible to issue a verified assessment for disinfectant products whose content of **1- or 2-propanol or ethanol is below the concentrations permitted** in the Extraordinary Decree of the German Federal Institute for Safety and Health (BAuA) and which are being marketed without a VAH Certificate, RKI Listing or which have not yet been authorized by the BAuA.

Therefore, the VAH recommends that every user – whether occupational or non-occupational – purchase disinfectants only following advice from pharmacists or infection control / hygiene personnel. The latter can in cases of doubt also request expert opinions from companies, based on which an assessment can then be made.

Purchasing hand disinfectants: Quality marks that must be met

QUALITY MARKS	SOURCE	DISINFECTANT MAY BE PURCHASED AND USED BY	INTENDED PURPOSE OF DISINFECTANT
VAH CERTIFIED AND LISTED	Source: Link to VAH List [2] Area of application: Hygienic hand disinfection Spectra of action: bactericidal, yeasticidal, virucidal (enveloped viruses) (or limited spectrum of virucidal activity, or virucidal (all viruses including non-enveloped viruses)	Any consumer	Routine disinfection Targeted disinfection
RKI LISTED	Source: Link to RKI List [3] Area of application: Hygienic hand disinfection Spectra of action: "AB" (or "A + virucidal (enveloped)", or "A + limited spectrum of virucidal activity"); observe use instructions	Any consumer	In particular, by official order, e.g. to fight clusters of pathogens or specific pathogens (e.g. anthrax)

EXCEPTIONAL SITUATION FOR COVID-19 IN THE ABSENCE OF QUALITY ASSURED, COMMERCIALLY AVAILABLE PRODUCTS			
QUALITY MARKS	SOURCE	DISINFECTANT MAY BE PURCHASED AND USED BY	INTENDED PURPOSE OF DISINFECTANT
GENERAL DECREE BY THE GERMAN FEDERAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (BAUA) OF 9 APRIL 2020, UPDATED VERSION FROM 15 APRIL 2020, TEMPORARY AUTHORIZATION UNTIL 6 OCTOBER 2020	<p>Source: Link to BAuA Decree [1]</p> <p>This General Decree lists 8 formulations. Detailed comparison of the product information against these formulations is recommended. They contain as principal active substance the following substances:</p> <ol style="list-style-type: none">1. 2-propanol 75% (v/v) (formulation with glycerol)2. 2-propanol 81.3% (v/v) (formulation with glycerol)3. 2-propanol 70% (v/v) (formulation without glycerol)4. Ethanol 80% (v/v) (formulation with glycerol)5. Ethanol 85.5% (v/v) (formulation with glycerol)6. Ethanol 70% (v/v) formulation without glycerol)7. Ethanol 80% (v/v) (formulation without glycerol)8. 1-propanol 70% (v/v) (formulation without glycerol)	<p>Sale to occupational users* and consumers permitted</p> <p>Formulation 8: sale restricted to occupational users*</p>	<p>Intended purpose: Routine and specific disinfection if there is no quality-assured and certified commercially available product.</p> <p>Note: Preference should be given to formulations 2 and 5 (<u>with glycerol</u>) or, as applicable, also 3 or 7, because with a contact time of 30 s, in addition to the spectrum of action "limited virucidal" (important for use against SARS-CoV-2), these also meet the quality requirements for efficacy against bacteria and yeasts.</p>

***Occupational users** within the meaning of the General Decree of 9 April 2020 include, in particular, public health institutions such as hospitals, medical practitioner offices, health centres as well as nursing homes and government institutions, such as town halls, public health offices, etc. However, products can also be supplied to companies and businesses to be used on site by their employees.

It is sufficient when the seller is able to confirm that based on the circumstances it is adequately clear that the purchaser belongs to one of the aforementioned institutions. **It is recommended** that occupational users who must regularly disinfect their hands throughout the day (such as e.g. doctors and nurses) use **products with glycerol**. Provision of advice at the time of sale is useful (BAuA General Decree [1]).

It is urgently advised not to use chlorine-based products for hand disinfection because of the **instability** and **skin irritation** potential of the now commercially available chlorine-based products.

Remarks about the approval of biocidal products by the German Federal Institute for Occupational Safety and Health (BAuA)

Under product type 01 the German BAuA has currently **approved** four biocidal products as disinfectants for human infection control/hygiene. But that product type also includes products intended for hygienic hand washing. These four approved and authorized products contain lactic acid as active substance. They are not recommended for hand disinfection in patient care settings or areas where an effective disinfectant action is desirable against bacteria, yeasts and enveloped viruses ([Link to BAuA Database \[4\]](#)). In general, biocidal products intended for hygienic hand washing are not an alternative to hand disinfectants.

As stated in the aforementioned BAuA General Decree, formulations 2 and 5 as well as formulations 3 or 7 should be used for inpatient and outpatient care, “if the efficacy requirements set out in EN 1500 for bactericidal efficacy within 30 s are to be met” [1]. But based on that General Decree, formulations are **also authorized** for the production and placement on the market of hand disinfectants containing the **active substances mentioned** in the formulations (see table) and “for which **either** a virucidal efficacy against enveloped viruses **or** a bactericidal, yeasticidal and virucidal efficacy against enveloped viruses has been demonstrated and for which pursuant to Article 89(3) of Regulation (EU) No. 528/2012 an **authorization application** was made on time” [1].

A BAuA **Registration Number** (N-XXXXXX) must not be confused with an **Authorization (Number)** (identifiable by means of the authorization number format EU-XXXXXXXX-XXXX or DE-XXXXXXXX-XX-XXXX-XX). For this registration number **only a formal application** as per the nationally applicable Biocide Notification Regulation **is needed** ([Link to the BAuA Transitional Regulations \[5\]](#)). This does not yet entail any efficacy testing. Currently, no provision is made for quality monitoring at state level. It is advisable to consult a certificate of analysis of alcohol purity if purchasing such a product.

Summary

From the perspective of the VAH, the following products are recommended when hand disinfection is indicated:

- VAH listed (spectra of action: bactericidal, yeasticidal + virucidal against enveloped viruses (or plus limited virucidal activity, or virucidal activity),
- RKI listed (spectra of action: “AB” (or “A + virucidal against enveloped”, or “A + limited spectrum of virucidal activity”).

If there are neither VAH- nor RKI-listed commercially available products,

- Products with the formulations 2 and 5 (as well as 3 and 7) as per the BAuA Extraordinary Decree (version of 15 April, see also table above).

The following are not recommended:

- Chlorine-based products for hand disinfection,
- Products with BAuA registration number with formulations other than the aforementioned and for which no certificate of analysis of alcohol purity has been issued.

This Memorandum was compiled in consensus with the Disinfectant Commission of the German Association for Applied Hygiene (VAH) and the VAH Applied Disinfection Working Group.

References

1. German Federal Institute for Occupational Safety and Health (BAuA). General Decree for authorization of 2-propanol-based and ethanol-based biocidal products for hygienic hand disinfection and sale to, and use by, occupational users and consumers as well as for authorization of 1-propanol-based biocidal products for hygienic hand disinfection and sale to, and use by, occupational users because of the risk to public health and for repeal of the General Decrees of 4 and 20 March 2020, version of 15 April 2020. (File numbers 710 30/01.00001 and 710 30/01.00002). Downloaded on 25 April 2020:https://www.baua.de/DE/Angebote/Aktuelles/Meldungen/2020/pdf/Allgemeinverfuegung-Haendedesinfektion.pdf?__blob=publicationFile&v=6.

2. VAH (Eds). VAH List of Disinfectants. Online Platform (English) <https://vah-liste.mhp-verlag.de/en/>
3. Robert Koch Institute (RKI). List of disinfectants and processes tested and recognized by the Robert Koch Institute. <https://link.springer.com/article/10.1007/s00103-017-2634-6>. Last viewed on 4 May 2020.
4. German Federal Institute for Occupational Safety and Health (BAuA). BAuA Database. https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Chemikalienrecht/Biozide/Datenbank-Biozide/Biozide_form.html?resourceId=868464&input_=868464&pageLocale=de&searchEngineQueryString=&prodart=01+%-28Desinfektionsmittel+f%C3%BCr+-die+menschliche+Hygiene%29&prodart.GROUP=1&wirkstoff=&wirkstoff.GROUP=1&submit=Suchen. Last viewed on 4 May 2020.
5. German Federal Institute for Occupational Safety and Health (BAuA). BAuA Transitional Regulations. https://www.reach-clp-biozid-helpdesk.de/DE/Biozide/biocidal_products/Uebergang/Uebergang_node.html. Last viewed on 4 May 2020.

Additional information on hand disinfection, etc. can be found on the following websites:

VAH website: www.vah-online.de

RKI website: www.rki.de

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