Joint Communication by the VAH Disinfectants Commission
and the Virus Disinfection Commission of the DVV and GfV

Harmonization of the Requirements for the Virucidal Activity of Chemical Surface Disinfection Procedures in the Simulated-Use Test

As of 25 February 2023

Introduction

In Germany, the activity spectrum of disinfection procedures against viruses currently comprises the following three activity levels:

1. Active against enveloped viruses
2. Limited spectrum of virucidal activity
3. Virucidal activity

Depending on risk assessment and the disinfectant application area (hands, surfaces, instruments, and laundry), different activity spectrums are required and can be claimed based on existing standardized test methods.

- For hygienic hand disinfection: active against enveloped viruses, limited spectrum of virucidal activity, virucidal activity
- For surface disinfection: active against enveloped viruses, limited spectrum of virucidal activity, virucidal activity
- For instrument disinfection: active against enveloped viruses, virucidal activity
- For textile disinfection: virucidal activity[1]

Current situation: Different requirements for the claim 'virucidal activity' for surface disinfection procedures

For evaluation of the virucidal activity of disinfectants, a two-step (tiered) procedure is used at both, national level within Germany (i.e. VAH in collaboration with DVV/GfV) and at European level (EN standards). Using that approach, the efficacy is confirmed in quantitative suspension tests (phase 2, step 1) and in simulated-use tests/tests conducted (phase 2, step 2).

However, at European level, harmonized simulated-use tests (phase 2, step 2 tests) to assess the virucidal activity spectrum are currently available only for surface disinfection using the spray method (application without mechanical action, EN 16777:2019-03) as well as for chemical and chemothermal instrument disinfection with the immersion method (EN 17111:2018-12) [1]. Further simulated-use tests are under preparation.

In Germany, labelling of the virucidal activity of a product, e.g. as a "virucide", by the manufacturer is not uniformly regulated so far. The product label must indicate the application area (e.g. food sector, medical area, institutional setting) and the instructions for use, but not the test methods and requirements on which the virucidal activity claim is based.

[1] Note: the limited spectrum of virucidal activiity is currently being revised in EN 14476

Accordingly, a manufacturer can state and advertise the virucidal activity of a surface disinfection method with mechanical action even if only a quantitative suspension test (based on DIN EN 14476:2019-10 or the DVV/RKI Guideline from 2015 [1]) and no simulated-use test was used. However, according to the statement issued by the Virucidal Activity Working Group at the Robert Koch Institute (RKI) [2], as soon as recognized test methods become available for simulated-use tests, they must be used as the basis for declaration of the application conditions.

- At European level, and as also stipulated by the **German Federal Institute for Safety and Health** (**BauA)** (for as long as no simulated-use tests with mechanical action are available), only the suspension test (phase 2, step 1) is currently required for the certification of surface disinfection procedures as a **Biocide (PT2)** for **application with mechanical action** (the simulated-use test for application without mechanical action is not needed either). For the conformity assessment of a surface disinfectant as a **medical device,** the manufacturer must provide, for the intended purpose of the product, proof of confirmation of the virucidal activity according to the state of the art [3].
- For certification of the virucidal activity, **VAH** requires in principle simulated-use tests, provided that these have been published (as per DVV/GfV or as per the EN standards). For certification of the virucidal activity of surface disinfection procedures with mechanical action (and wiping), the VAH requirements specify the simulated-use test without wiping until such time as the draft for the test method with mechanical action (4-field test for the virucidal activity) has been adopted [4].
- For declaration of the virucidal activity in its Disinfectants List, the **Robert Koch Institute** has compiled its own simulated-use tests for officially decreed disinfection measures and, for historic reasons, declared the virucidal activity as “activity spectrum B”. This activity spectrum B covers enveloped as well as non-enveloped viruses in accordance with the definition of the “virucidal activity” of the RKI’s Virucidal Activity Working Group [2].

Conclusion: The declaration or labelling of products as being endowed with “active against enveloped viruses”, “limited spectrum of virucidal activity” or “virucidal activity” does not mean that the products will have undergone the same tests or meet the same requirements for confirmation of this activity. This applies not just for surface disinfection procedures but also for other areas where chemical disinfection procedures are used.

Requirements for efficacy testing of the virucidal activity in simulated-use tests for surface disinfection with mechanical action

Special attention is paid to the “virucidal activity” spectrum for surface disinfection. The declaration “virucidal activity” has changed in recent years in line with the development of new European standards. In particular, hitherto there is no congruence between the “virucidal activity” as defined in EN standards and “virucidal activity” as per the DVV/GfV and VAH definition.
The virucidal activity is of paramount importance, in particular, for disinfection of medical devices, which also includes the disinfection of medical devices with products marketed as surface disinfectants. The applicable *KRINKO/BfArM Recommendation** requires virucidal activity for disinfection of semi-critical as well as critical medical devices (if not followed by sterilization) [5].

Apart from reprocessing medical device surfaces, the virucidal activity of surface disinfectants is reserved for special indications (see *KRINKO* recommendation for cleaning and disinfection of surfaces, 2022 [6] as well as framework hygiene policies formulated for communal facilities by the German Federal States Working Group).

**KRINKO/BfArM Recommendation*: Hygiene requirements for reprocessing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (*BfArM)*

Harmonization of the virucidal activity spectrum for surface disinfection

For declaration of the virucidal activity for simulated-use efficacy tests (phase 2, step 2), the DVV/GfV and VAH have hitherto required, in addition to adeno- and norovirus, murine parvovirus as test virus [2]. This allows in the simulated-use test, too, confirmation of activity against strongly hydrophilic non-enveloped viruses such as parvoviridae and poliovirus [see classification by Rabenau and Schwebke in (7)], because the poliovirus used to that effect in the suspension test cannot be employed in the simulated-use test due to its loss in titre after drying on the test surface [8].

However, the current European standards for simulated-use tests published in recent years or the new draft standards do not include murine parvovirus as test organism for the virucidal activity of surface disinfection. Poliovirus is used as test organism to demonstrate activity against e.g. enteroviruses in the suspension test.

Murine parvovirus is used as a surrogate virus, in particular, to demonstrate activity against parvoviridae, including adeno-associated viruses (among other things, in gene therapy). However, it has a high tolerance to alcohol-based substances [9]. Hence, alcohol-based products are not able to inactivate parvoviridae. High tolerance to alcohol has also been observed for hepatitis E viruses [10]. Likewise, hepatitis A virus has proved resistant to alcohol-based hand disinfectants [7, 10, 11, 12].

However, for declaration of the virucidal activity for surface disinfection without mechanical action, activity against murine parvovirus was confirmed for products based on peracetic acid, aldehydes, oxygen scavengers and chloramine-T in simulated-use tests in various test laboratories [13, 14].

Routine stipulation of murine parvovirus as test organism in the simulated-use test for surface disinfection is problematic because, first, the active ingredient concentration and contact (exposure) time of a product for confirmation of activity against parvovirus e.g. compared with other clinically relevant non-enveloped viruses, must be significantly increased and, second, the choice of possible substances is restricted.

Declaration of the virucidal activity is therefore to be broken down in future into two levels: **virucidal activity** and **virucidal activity PLUS**. This will also ensure harmonization with the test organisms specified in the European standards for the healthcare setting and thus create a uniform basis for claiming “virucidal activity“ in the simulated-use test.

As such, virucidal products continue to be the correct choice for all indications targeting enveloped and the most common non-enveloped viruses for surface disinfection applications, including the disinfection of medical devices.

If disinfection is required to prevent the transmission of viruses that are particularly tolerant to disinfectants, such as HAV, HEV, parvoviridae – including adeno-associated viruses as well as oncolytic parvoviruses in gene therapy – proof of activity against parvoviruses must also be provided and the new virucidal activity PLUS spectrum selected (Table 1).

The precise indications for disinfection with the “virucidal activity PLUS” claim must be formulated by the responsible hospital infection control specialists as well as by public health as well as laboratory personnel. For laboratory tasks involving genetically modified viruses and viral vectors, the DVV and GfV have issued a helpful statement [8].

***Table 1**: Harmonization of the requirements for the virucidal activity of disinfectants used in surface disinfection, simulated-use tests (phase 2/step 2)*

(Translation of the) German terms and activity spectrum **VAH List** **German standards** ***KRINKO* recommendations**	**English terms and reference to the European standards**	**Test viruses for the quantitative suspension test** (as per DVV/GfV and VAH) **Surface disinfection with and without mechanical action** **Requirement for VAH certification**	**Test viruses for simulated-use tests** Proposal by DVV/GfV and VAH **Surface disinfection with and without mechanical action** **Requirement for VAH certification**
Active against enveloped viruses Efficacy against • Enveloped viruses	Corresponds to the term *Active against enveloped viruses* as per EN standards	Vaccinia virus BVDV (for products with oxidative activity)	Vaccinia virus
Limited spectrum of virucidal activity Efficacy against enveloped viruses **plus** • Adenovirus • Norovirus • Rotavirus	Corresponds to the term *Limited spectrum of virucidal activity* as per EN standards	Adenovirus Norovirus	Adenovirus Norovirus
Virucidal activity Same activity level as limited spectrum of virucidal activity PLUS as well as additionally active against non-enveloped viruses such as e.g. • Papillomaviruses • Picornaviridae, including enteroviruses, but not HAV	Corresponds to the term *Virucidal* activity as per EN standards	Adenovirus Norovirus Poliovirus SV 40*	Adenovirus Norovirus[1]
Virucidal activity PLUS Same activity level as virucidal activity and additionally active against non-enveloped viruses such as e.g. • Parvoviridae (including adeno-associated viruses, native onco-lytic parvoviruses**)** • Hepatitis A viruses • Hepatitis E viruses	There is currently no corresponding term in the EN standards	Adenovirus Norovirus Poliovirus SV 40	Adenovirus Norovirus Parvovirus

*In addition to the test organisms stipulated in the European standards
[1]The extension of the virucidal activity spectrum in comparison to the limited spectrum of virucidal activity is based on the test organisms required for the suspension test.

In future, users will find products claiming **"virucidal activity PLUS"** in the VAH List under "surface disinfection". Accordingly, once the revised requirements have come into force, a distinction will be made in the VAH List between **virucidal activity** and **virucidal activity PLUS** for surface disinfection.

Outlook

The requirements for VAH certification of the virucidal activity for surface disinfectants (with and without mechanical action) will be revised – after consultation with *KRINKO* - and updated in the publication "Requirements and Methods for VAH Certification of Chemical Disinfection Procedures", Chapter V2.

The "virucidal activity" spectrum based on DVV/GfV and VAH thus corresponds to the "virucidal activity" spectrum based on the current EN standards in the simulated-use test. However, with the introduction of the new "virucidal activity PLUS" spectrum, it is possible to make an additional claim for viruses with a particularly high tolerance to disinfectants. This is also in line with the strategy for targeted hygiene in disinfection and contributes to harmonization of national and European Standards.

Regardless of this, the VAH continues to call for test reports from two independent laboratories and two manufacturer-independent expert opinions for all activity spectrums, setting out the application recommendations resulting from testing, as a prerequisite for certification of a product as well as proof of activity in the simulated-use test as per the already published guidelines and standards.

References

1. Desinfektionsmittel-Kommission im VAH. Desinfektionsmitteltestung gemäß den VAH-Methoden und den Anforderungen für die VAH-Listung oder Testung nach europäischen Normen – was ist der Unterschied? HygMed 2022;190-193.
2. Schwebke I, Eggers M, Gebel J, Geisel B, Glebe D, Rapp I, Steinmann J, Rabenau F. Prüfung und Deklaration der Wirksamkeit von Desinfektionsmitteln gegen Viren zur Anwendung im human-medizinischen Bereich: Stellungnahme des Arbeitskreises Viruzidie beim Robert Koch-Institut. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2017 Mar;60(3):353-363. German. doi: 10.1007/s00103-016-2509-2. PMID: 28220216; PMCID: PMC7079851.
3. Jäkel C. Qualitätskriterien, Wirksamkeitstests und Voraussetzungen der Verkehrsfähigkeit von Desinfektionsmitteln als Medizinprodukte. HygMed 2022;47(11):236-242. [Online im Internet] https://vah-online.de/files/download/vah-mitteilungen/VAH_Verkehrsf%C3%A4higkeit_Desinfektionsmittel_Medizinprodukte%20HM_11_22.pdf
4. Arbeitsgruppe Viruswirksamkeit der Desinfektionsmittel-Kommission im VAH. Anforderungen an die Viruswirksamkeit (Anhang V), Stand 1.11.21. In: Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Ergänzungen mit Stand 1.9.2022. [Online im Internet] https://vah-online.de/files/download/ebooks/eBook_VAH_Methoden_Anforderungen.pdf
5. Kommission für Krankenhausyhgiene und Infektionsprävention beim Robert Koch-Institut und des Bundesinstitutes für Arzneimittel und Medizinprodukte. Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsbl 2012;55:1244-1310.
6. Kommission für Krankenhausyhgiene und Infektionsprävention beim Robert Koch-Institut. Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen. Bundesgesundheitsbl 2022;65:1074-1115.
7. Rabenau HF, Schwebke I. Hygiene und Desinfektion zur Bekämpfung von Viren. In Doerr HW et al: Medizinische Virologie. Stuttgart: Thieme, 2010.
8. Eggers M, Rabenau HF, Blümel J, Fickenscher H, Geisel B, Glebe D, et al. Einsatz geeigneter Desinfektionsmitteln bei gentechnisch veränderten Viren und viralen Vektoren: Stellungnahme der Kommission für Virusdesinfektion der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e. V. und der Gesellschaft für Virologie (GfV) e. V. Epid Bull 2020;35:3-14 | DOI 10.25646/7030 .
9. Eterpi M, McDonnell G, Thomas V. Disinfection efficacy against parvoviruses compared with reference viruses. J Hosp Infect. 2009 Sep;73(1):64-70. doi: 10.1016/j.jhin.2009.05.016. Epub 2009 Jul 30. PMID: 19646784.
10. Behrendt P, Friesland M, Wißmann JE, Kinast V, Stahl Y, Praditya D, et al. Hepatitis E virus is highly resistant to alcohol-based disinfectants. J Hepatol. 2022 May;76(5):1062-1069. doi: 10.1016/j.jhep.2022.01.006. Epub 2022 Jan 24. PMID: 35085595.
11. von Rheinbaben, F. & Wolff, M. H. Handbuch der viruswirksamen Desinfektionen (Springer, 2002). https://doi.org/10.1007/978-3-642-56394-2_13

12. Kampf G. Efficacy of ethanol against viruses in hand disinfection. J Hosp Infect 2018;98(4):33-1338.
13. Rabenau HF, Steinmann J, Rapp I, Schwebke I, Eggers M. Evaluation of a Virucidal Quantitative Carrier Test for Surface Disinfectants. PLOS ONE 2014; 9(1): e86128. https://doi.org/10.1371/journal.pone.0086128
14. Robert Koch-Institut. Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren. Bundesgesundheitsblatt 2017:1274–1297 sowie Nachträge.

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