Notification by the Disinfectants Commission of the German Association of Applied Hygiene (VAH)

New efficacy spectrum “limited virucidal activity PLUS” – what is that?

In Germany, since 2004 disinfectants have been classified in terms of their virucidal activity/efficacy as follows:
- limited virucidal activity and
- virucidal activity [1].

The “limited virucidal activity” spectrum includes only enveloped viruses, while the “virucidal activity” range includes all viruses.

In terms of virucidal efficacy, limited virucidal activity constitutes the minimum requirement to be met by a disinfectant. Efficacy against enveloped viruses covers the most important viruses with higher pathogenic priority [2] such as e.g. HIV, HBV and HCV, as well as influenza viruses, respiratory syncytial virus (RSV) or Ebola virus (Fig. 1). This, so to say, represents the first efficacy level of virucidal disinfection.

The most recent recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) for hand hygiene in healthcare institutions introduces a new virucidal efficacy level for prophylactic hand disinfection: Limited virucidal activity PLUS. “In settings where there is a risk of transmission of enveloped viruses, hand disinfectants (HDM) with limited virucidal activity should be used; where there is a risk of transmission of non-enveloped viruses, products with limited virucidal activity Plus or virucidal HDMs should be used, depending on the virus species [Cat. IBI]”. This new virucidal disinfection efficacy level 2 includes, in addition to activity against enveloped viruses, efficacy against noro-, aden- and rotaviruses (see also Fig. 2). In epidemiological terms, these three non-enveloped viruses are the viral pathogens most commonly implicated in infections in inpatient and outpatient medical establishments and in public institutions. One advantage of this extended efficacy spectrum is that the same disinfectants can be used for prophylactic disinfection throughout the entire year, thus obviating the need to switch to other products because of the seasonal changes occurring in the viral pathogens.

Efficacy level 3, representing the highest level of virucidal disinfection, includes virucidal processes covering all viruses (Fig. 3). Virucidal products should therefore be used e.g. for disinfection in outbreaks of hand, foot and mouth infections caused by enteroviruses. They are also effective against enterovirus D68, which in 2014 was responsible for the cases of acute flaccid paralysis in Norway and the Netherlands. Enterovirus 71 or polioviruses cause similar symptoms and call for virucidal disinfectants and processes.

Details of virucidal products for routine disinfection can be found on the List of Disinfectants Approved by the Association of Applied Hygiene (VAH List) or (when officially mandated) on the RKI List of Disinfectants. The VAH List features only products that meet the test requirements of the German Association for Control of Viral Diseases (DVV) and VAH as well as European standards, and which had undergone a conformity assessment procedure by independent experts of the VAH Disinfectants Commission. Information will be published in the near future on listing products with declared “limited virucidal activity PLUS”. The criteria to be met for inclusion on the list will be based on the updated notification by the RKI’s Virucidal Efficacy Working Group to be soon published.

These three efficacy levels are new with regard to virucidal activity. But the efficacy levels against bacteria also feature different spectrums of activity determined by the various bacterial properties: what is required in principle is bactericidal activity. Additionally, tuberculocidal, mycobacterial and sporicidal efficacy spectrums can be tested and certified.

When selecting products for hand disinfection (HDM) it should be noted that in general for inactivation of non-enveloped viruses, products with high ethanol concentration or synergistic combinations with lower alcohol content and e.g. acids are effective. Products containing only propanols are not endowed with adequate virucidal activity because of their short exposure time. With the advent of the effic-
Limited virucidal activity (enveloped viruses)

**Test Virus**
- Vaccinia virus (Elstree strain and/or MVA) enveloped
- [BVDV (bovine viral diarrhoea virus)]

**Efficacy Spectrum (examples)**
- Viruses causing bloodborne infections
  - Hepatitis B virus (HBV)
  - Hepatitis C virus (HCV)
  - Human immunodeficiency virus (HIV)
- Viruses causing respiratory infections
  - Human coronavirus (HCoV) 229E and OC43
  - Influenza virus A (e.g. H1N1, H3N2) and B
  - Metapneumonievirus
  - Respiratory syncytial virus (RSV)
- Viruses causing travel-associated infections
  - Bunyavirus (sandfly fever)
  - Dengue virus, Ebola virus, yellow fever virus, hantavirus, Lassa virus, Marburg virus, zikavirus
  - Crimean-Congo haemorrhagic fever virus
  - Tickborne spring/summer meningoencephalitis virus
  - SARS-CoV, MERS-CoV
  - Rabies virus
  - West Nile virus (West Nile fever)
- Herpesviruses
  - Cytomegalievirus (CMV)
  - Herpes simplex virus type 1 and 2 (HSV-1, HSV-2)
  - Epstein-Barr virus (EBV)
  - Varicella zoster virus (VZV)
- Paramyxovirus
  - Measles virus
  - Mumps virus
- Rubella virus

**Figure 1: Efficacy level 1: limited virucidal activity**

Limited spectrum of virucidal activity

**Test Virus**
- Adenovirus (Adenovirus type 5, strain Adenoid 75) non-enveloped
- Murine norovirus (MNV – strain: S99 Berlin) non-enveloped

**Efficacy Spectrum (examples)**
- Viruses causing respiratory infections
  - Adenovirus (incl. serotype 7)
- Viruses causing der keratoconjunctivitis
  - Adenovirus (incl. serotype 8, 19 and 37)
- Erreger der Keratokonjunktivitis
  - Adenovirus (u.a. Serotyp 8, 19 und 37)
- Enveloped viruses (see limited virucidal activity)

**Figure 2: Efficacy level 2: limited virucidal activity PLUS.**
In general, expert advice is needed to select the required spectrum of action and suitable disinfectant [4]. In addition to the lists mentioned above, users can consult the online VAH List which, thanks to an improved search system, they will find easier to navigate for an overview of viruses and efficacy spectrums.

The three-level concept of virucidal activity permits well-target selection of products tailored to the risk presented by the respective viruses and will in future constitute the method of choice for selection of virucidal disinfection processes.

**References**

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<tr>
<th>Test Virus</th>
<th>Efficacy Spectrum (examples)</th>
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| Adenovirus (adenovirus type 5, strain Adenoid 75) | Paroviruses  
| non-enveloped | – Parovirus B19  
| | – Bocavirus |
| Murine norovirus (MNV – strain: S99 Berlin) | Picornaviruses  
| non-enveloped | – Enteroviruses: Coxsackieviruses, Echoviruses, polioviruses, rhinoviruses  
| | – Hepatovirus: hepatitis A virus (HAV)  
| | – Parechoviruses: Echovirus 22 and 23 |
| Poliovirus (poliovirus type I, strain LSc-2ab) | Hepeviridae  
| non-enveloped | – Hepatitis E virus |
| Polyomavirus SV40 (strain 777, surrogate for HPV) | Viruses causing gastroenteritis  
| non-enveloped | – Adenovirus (incl. serotype 40 and 41)  
| | – Norovirus  
| | – Rotavirus |
| Parvoviruses | Viruses causing respiratory infections |
| Murine norovirus | – Adenovirus (incl. serotype 7)  
| | – Norovirus  
| | – Rotavirus |
| Polyomavirus SV40 | Viruses causing keratoconjunctivitis  
| non-enveloped | – Adenovirus (incl. serotype 8, 19 and 37) |
| | Enveloped viruses (see limited virucidal activity) |

**Figure 3: Efficacy level 3: virucidal activity.**
Recommendation for selection of sporicidal disinfectants against Clostridium difficile infections in human medicine

Clostridium difficile infections (CDIs) necessitate the use of sporicidal disinfectants to effectively inactivate any endospores also present and interrupt the infection chain. But the difficulty is in selecting a suitable disinfectant with proven sporicidal efficacy since to date there are no approved and harmonized test methods available to that effect. Therefore, current declarations of sporicidal efficacy are based on existing EN standards regulating other application areas, which through extensive changes have been adapted to sporicidal efficacy testing in human medicine. This gives rise to the problem that when evaluating sporidal products there is frequent variation between products with regard to spore enrichment, test organisms (strain) used, baseline suspension and sensitivity of spores, challenge substances and required reduction rates which, consequently, does not permit comparability or appropriate efficacy testing.

The October issue of Hygiene & Medizin 2016 / Infection Control and Healthcare (HygMed 2016; 41(10): 271) published an approved test method for sporicidal efficacy testing against C. difficile spores drawn up by the VAH Disinfectants Commission and the 4+4 Working Group, reflecting the current state of knowledge. In parallel, the same method was submitted to the enquiry process at CEN TC 216 as Work Item (WI) 216068, status 2017-01.

For C. difficile infection prophylaxis the Disinfectants Commission recommends the use of sporicidal disinfectants whose sporicidal properties have been tested with at least VAH method 18 or Work Item 216068, status 2017-01. For C. difficile infection prophylaxis the Disinfectants Commission recommends the use of sporicidal disinfectants whose sporicidal properties have been tested with at least VAH method 18 or Work Item 216068, status 2017-01. For wipe impregnation systems the impregnation solution, and for ready-to-use wipe systems the expressed impregnation solution, should be tested with the aforementioned test methods, while observing the disinfectant stability in both cases.

For routine disinfection of rooms accommodating CDI patients the Disinfectants Commission recommends daily surface disinfection with a product with proven sporicidal efficacy, in at least a bactericidal/levuricidal concentration-time relationship. The reason put forward for that was that often patients were unable to tolerate the disinfectant substance as used in the sporicidal concentration-time relationship when patient persons are present in the room.

However, for terminal disinfection or in outbreak settings the sporicidal concentration-time relationships of a product’s with proven sporicidal efficacy must always be used.

The VAH Disinfectants Commission and the 4+4 Working Group are also currently developing a practice-oriented test method based on the 4-field test of VAH method 14.2 and EN 16616. The VAH is also at present drawing up a list of such sporicidal products.

References


Other VAH publications: www.vah-online.de