

# Essential Requirements and Test Methods for VAH-Certification of Chemical Disinfectant Products and Procedures

Please note:

This Chapter is an excerpt of the print edition of the VAH Disinfectants List. It serves only as an orientational guide to the test methodology and requirements. A complete and binding description is given in the German language publication *Requirements and Methods for VAH Certification of Chemical Disinfection Procedures* on the VAH website [1]. The translation of the German version of this Chapter has been modified to include References of all relevant EN Standards.

## HYGIENIC HAND WASHING PROCEDURES

### Explanatory Notes on the Test Methodology

The following requirements must be met to certify hygienic handwashing products [1]:

Bactericidal and yeasticidal (*C. albicans*) efficacy must be demonstrated.

1. *To that effect, the following orientational preliminary tests can be conducted:*

- Determination of bacteriostatic and yeastistatic activity as well as of suitable neutralizers (Method 7).
- Determination of bactericidal and yeasticidal activity in the qualitative suspension test (Method 8).

2. *The following tests are obligatory:*

- *Phase 2/Step 1:* Determination of bactericidal and yeasticidal activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]) at 20 °C, with a 50 % concentration (final concentration in the test) and as a concentrate (in addition to the concentrations required for assessment of the activity limit), using a high organic challenge at 15 s, 30 s and 1 min.

At 50% of the use concentration, the test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* in the qualitative suspension test or if no qualitative suspension test was carried out), using a high organic challenge and within the recommended contact time (30 s or 1 min) at 20 °C, by at least 3 lg levels and *C. albicans* by at least 2 lg levels.

- *Phase 2/Step 2:* Hygienic handwashing – simulated-use test with volunteers (Method 10) (DIN EN 1499 [4]). To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:
  - Complete and evaluable results must be available for at least 12 of the 15 volunteers.
  - The logarithmic (lg) total mean of the pre-values for the reference and the test procedure(s) must be at least 5.

If the mean of the lg reduction factor of the test product is significantly greater than that of the soap-based reference procedure, the test product meets the requirements under simulated-use conditions.

### References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel 10, [Stand: April 2025]. Verfügbar unter: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025].
2. DIN EN 13727:2012+A2:2015. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13727:2012+A2:2015.

3. DIN EN 13624:2022-08. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13624:2021.
4. DIN EN 1499:2017-10. Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2); German version EN 1499:2013

## HAND DISINFECTION

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### Explanatory Notes on the Test Methodology

#### 1 Hygienic Hand Disinfection (*hygienic handrub, hand antisepsis*)

The following requirements must be met to certify hygienic hand disinfection [1]:

As a minimum requirement, bactericidal and yeasticidal (*C. albicans*) efficacy must be demonstrated.

1. To that effect, the following *orientational* preliminary tests can be conducted:

- Determination of bacteriostatic and yeastistatic activity as well as of suitable neutralizers (Method 7);
- Determination of bactericidal and yeasticidal activity in the qualitative suspension test (Method 8).

2. The following tests are *obligatory*:

- *Phase 2/Step 1*: Determination of bactericidal and yeasticidal activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]) at 20 °C as a concentrate (in addition to the concentrations required for assessment of the activity limit), using a high organic challenge at 15 s, 30 s and 1 min.

The test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* in the qualitative suspension test or if no qualitative suspension test was carried out), using a high organic challenge and within the recommended contact time (30 s or 1 min) at 20 °C, by at least 5 lg levels and *C. albicans* by at least 4 lg levels.

- *Phase 2/Step 2*: Hygienic hand disinfection – simulated-use test with volunteers (Method 11) (DIN EN 1500 [4]).

To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:

- Complete and evaluable results must be available for at least 18 of the 20 volunteers.
- The logarithmic (lg) total mean of the pre-values for the reference and the test procedure(s) must be at least 5 and
- because of the more stringent requirements for statistical analysis, the number of test results with a reduction of less than 3 lg levels may be adjusted to the actual number of volunteers evaluated. For example, for 30 evaluated volunteers, test results with a reduction of less than 3 lg levels may be increased from 3 to 4.

The difference between the mean reduction values must be tested for statistical significance. It must be demonstrated that the test product is not less effective than the propan-2-ol-based reference procedure (60 vol% application with 2 x 3 ml for 2 x 30 s). The test is performed according to the Hodges-Lehmann procedure.

Since 12 March 2021, the certificate and the VAH List of Disinfectants state the product volume used for testing [5].

In a communication published in May 2020, the Disinfectants Commission drew attention to hand disinfectants applied as foam. These, too, must be tested under simulated-use conditions, in accordance with the recommended application [6].

➤ **As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*).**

### *Listing Virucidal Properties*

*(For more detailed information, please refer to the General Preface)*

As announced in a VAH communication in August 2018 [9], the Disinfectants Commission decided to also assess the virucidal properties of products on the basis of test reports and expert opinions and include these in the VAH List, if requested by the companies (the applicant). The concentration-time relations for the activity spectrums *active against enveloped viruses, limited spectrum of virucidal activity* and/or *virucidal activity* are listed in a separate line in the product entry. Regardless of the concentration-time relations specified for virucidal activity in the expert opinions, the values listed for bactericidal and yeasticidal activity must be seen as minimum requirements for use. Therefore, the values specified in the VAH List for virucidal activity are never lower than those for bactericidal and yeasticidal activity. Products claiming *activity against enveloped viruses, limited spectrum of virucidal activity* and/or *virucidal activity* will have undergone a conformity assessment procedure conducted by independent experts of the Disinfectants Commission and based on two expert opinions (including the corresponding test reports) in accordance with the valid test methods [9–12]. For alcohol-based hand disinfectants for which only one expert opinion, with corresponding test report, is provided, a benchmark test may also be carried out for the activity spectrum *active against enveloped viruses* (s. Chapter V1B in [13]). For confirmation of limited spectrum of virucidal activity and/or virucidal activity a phase-2-step-2 test with the murine norovirus according to DIN EN 17430 [14] is additionally required.

*The following tests are obligatory:*

- *Phase 2/Step 1:* Determination of virucidal activity (activity spectrum: active against enveloped viruses, limited spectrum of virucidal activity, virucidal activity) in the quantitative suspension test (Method DVV/RKI 2005, 2008 or 2015 [9, 10, 11] or DIN EN 14476 [12] at 20 °C as a concentrate (in addition to the concentrations required for assessment of the activity limit), using a low organic challenge at 15 s, 30 s, 1 min, 1.5 min or 2 min. The test reports and expert opinions must meet the VAH requirements for virus activity [15].  
The test product must reduce the virus titre for the activity spectrum
  - active against enveloped viruses: against vaccinia virus and, for oxidizing products, additionally against BVDV,
  - limited spectrum of virucidal activity: against adenovirus and norovirus
  - virucidal activity: against poliovirus, adenovirus, norovirus and SV40 viruswithin the specified contact times(s) at 20 °C by at least 4 lg levels (for details please refer to Chapter V1 of the Requirements and Methods for VAH Certification [15]).
- *Phase 2/Step 2:* Hygienic hand disinfection – simulated-use test with volunteers (DIN EN 17430 [14]). To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:
  - Complete and evaluable results must be available for at least 18 volunteers.
  - The logarithmic (lg) total mean of the pre-values for the reference and the test procedure(s) must be at least 4 and
  - The reference product must not have more than three individual lg reductions < 2.
  - The difference between the mean reduction values must be tested for statistical significance. It must be demonstrated that the test product is not less effective than the ethanol-based reference procedure (70 vol% application with 2 x 3 ml for 2 x 30 s). The test is performed according to the Hodges-Lehmann procedure.

## 2 Surgical Hand Disinfection

The following requirements must be met to certify products for surgical hand disinfection [1]:

As a minimum requirement, bactericidal and yeasticidal (*C. albicans*) efficacy must be demonstrated.

1. To that effect, the following **orientational** preliminary tests can be conducted:

- Determination of bacteriostatic and yeaststatic activity as well as of suitable neutralizers (Method 7);
- Determination of bactericidal and yeasticidal activity in the qualitative suspension test (Method 8).

2. The following tests are **obligatory**:

- **Phase 2/Step 1:** Determination of bactericidal and yeasticidal activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]) at 20 °C as a concentrate (in addition to the concentrations required for assessment of the activity limit), using a low organic challenge at a minimum contact time of 1 min, 3 min or 5 min. If the contact time recommended by the manufacturer does not correspond to one of these test times, tests must be done with one contact time below and one contact time above (that time) as well.

The test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* or if no qualitative suspension test was carried out), using a low organic challenge and within the specified contact time (1–3 min, 5 min) at 20 °C, by at least 5 lg levels and *C. albicans* by at least 4 lg levels.

- **Phase 2/Step 2:** Surgical hand disinfection – simulated-use test with volunteers (Method 12) (DIN EN 12791 [7]).

To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:

- Complete and evaluable results must be available for at least 23 of the maximum 28 volunteers.
- The logarithmic (lg) total mean of the pre-values for the reference and the test procedure(s) must be at least 3.5.

If the mean of the lg reduction factor obtained for the immediate effect and the effect after 3 h of the test product is not significantly lower than that of the propan-1-ol-based reference procedure, the test product meets the requirements under simulated-use conditions.

The reference procedure is performed with 60 vol% propan-1-ol for 3 min. The test procedure may also be carried out with shorter contact times, but a minimum contact time of 1 min is required.

Furthermore, if the mean value of the lg reduction factor obtained for the sustained effect, after 3 h, of the test procedure is significantly greater than that of the propan-1-ol-based reference procedure, the test product meets the requirements under simulated-use conditions for a 'sustained effect' procedure.

➤ **As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*)**

## References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel 11 und 12. [Stand: April 2025]. Available: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025]
2. DIN EN 13727:2012+A2:2015. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13727:2012+A2:2015.
3. DIN EN 13624:2022-08. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13624:2021.

4. DIN EN 1500:2017-10. Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2); German version EN 1500:2013.
5. Desinfektionsmittel-Kommission im VAH. Volumenangaben zur Händedesinfektion in der VAH-Liste. Stand: 1. November 2021. HygMed 2021;46(11):242-243.
6. Desinfektionsmittel-Kommission im VAH (Hrsg.) Wirksamkeitsprüfung von alkoholischen Schäumen zur hygienischen Händedesinfektion. HygMed 2020;45(5):76–78.
7. DIN EN 12791:2018-01. Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2); German version EN 12791:2016+A1:2017.
8. Desinfektionsmittel-Kommission im VAH. Anforderung an die Zertifizierung von viruswirksamen Verfahren für die VAH-Liste - Modalitäten für die Antragstellung. HygMed 2018;43(7/8):141.
9. DVV, RKI. Leitlinie der DVV und des RKI zur Prüfung von chemischen Desinfektionsmitteln gegen Viren in der Humanmedizin. Bundesgesundheitsbl 2005;48:1420–1426.
10. DVV, RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin (Fassung vom 1. 8. 2008). HygMed 2008;33:315–322.
11. DVV, RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. Dezember 2014. Bundesgesundheitsbl 2015;58:493–504.
12. DIN EN 14476:2025-11. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1); German version EN 14476:2025.
13. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel V1B. [Stand: Januar 2025]. Available: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025]
14. DIN EN 17430:2024-05. Chemical disinfectants and antiseptics - Hygienic handrub virucidal - Test method and requirements (phase 2/step 2); German version EN 17430:2024.
15. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel V1A [Stand: September 2024] und V1B [Stand: April 2025]. Available: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025].

For English translations, also refer to: <https://vah-online.de/en/for-laboratories>

## SKIN ANTISEPSIS

### Explanatory Notes on the Test Methodology

The following requirements must be met to certify products for skin antiseptics [1]:

Bactericidal and yeasticidal (*C. albicans*) efficacy must be demonstrated.

1. To that effect, the following **orientational** preliminary tests can be conducted:

- Determination of bacteriostatic activity as well as of suitable neutralizers (Method 7).
- Determination of bactericidal activity in the qualitative suspension test (Method 8).

2. The following tests are **obligatory**:

- **Phase 2/Step 1:** Determination of bactericidal activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]) at 20 °C, using a high organic challenge at 15 s, 30 s, 1 min, 5 min or 10 min.

The test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* in the qualitative suspension test or if no qualitative suspension test was carried out), using a high organic challenge and within the recommended contact time (15 s, 30 s, 1 min, 3 min, 5 min or 1 min, 1.5 min, 2 min, 2.5 min, 3 min, 5 min, 10 min) at 20 °C, by at least 5 lg levels as well as *C. albicans* by at least 4 lg levels [1].

The following test method is **obligatory** to determine efficacy against the **resident** flora [1]:

- **Phase 2/Step 2:** Skin antiseptics (Method 13)

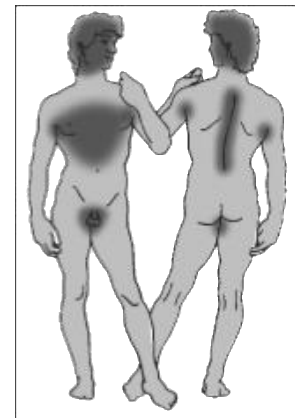
To compare the results of the test and reference procedures and evaluate the test procedure, the following requirements must be met:

- Complete and evaluable results must be available for at least 18 of the 20 volunteers.
- The logarithmic mean of all pre-values must be > 2.

If the mean value(s) of the reduction factor of the test procedure for the respective contact times is/are smaller than those of the reference procedure and if the difference is statistically corroborated for at least one mean value, the test product shall be rejected as being unsuitable.

This applies for skin that has both a low and a high density of sebaceous glands.

For declaration of efficacy on skin that has a low density of sebaceous glands, tests are carried out on the upper arms of volunteers, and on the forehead for declaration of efficacy on skin that has a high density of sebaceous glands (see **Figure 1**). The skin is not artificially contaminated with test bacteria for these tests; rather, proof of efficacy is based on existing bacterial colonization of the skin of each volunteer.



**Figure 1**

Low density of sebaceous glands (100 sebaceous glands/cm<sup>2</sup>)   
 High density of sebaceous glands (400 to 900 sebaceous glands/cm<sup>2</sup>)

- **As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*)**

## References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel 13 [Stand: April 2015]. Available: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025].
2. DIN EN 13727:2012+A2:2015. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13727:2012+A2:2015.
3. DIN EN 13624:2022-08. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13624:2021.

## SURFACE DISINFECTION

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### Introductory Remarks

The application area of surface disinfection in VAH List of Disinfectants contains only products/procedures which have demonstrated bactericidal and yeasticidal (*C. albicans*) efficacy as per the *Requirements and Methods for VAH Certification of Chemical Disinfection Procedures* [1] including the applicable amendments and updates of the relevant test methods.

In accordance with European standards, tests for surface disinfectants are conducted using low and/or high organic challenges in quantitative suspension tests and in tests under simulated-use conditions (contaminated germ carriers). Furthermore, a distinction is made between applications that involve “*without mechanical action*” (spraying only) and “*with mechanical action*” (wiping). Efficacy against *S. aureus*, *E. hirae*, *P. aeruginosa*, *E. coli*\*, *P. mirabilis*\* (to be tested in the quantitative suspension test, if this had proved to be more resistant than *P. aeruginosa* in the qualitative suspension test or if no qualitative suspension test was carried out) and *C. albicans* must be demonstrated for each concentration-time relation specified for a product in this section.

Efficacy against *M. terrae* (tuberculocidal activity), *M. avium* (mycobactericidal activity), *A. brasiliensis* (fungicidal activity) and *C. difficile spores* (sporicidal activity) may be claimed additionally.

### Explanatory Notes on the Test Methodology

#### Bacteria and Fungi

1. The following *orientational* preliminary tests can be carried out to certify products for surface disinfection:
  - Determination of bacteriostatic and yeasticidal activity as well as of suitable neutralizers (Method 7) (not for *M. terrae*, *M. avium*, *A. brasiliensis*).
  - Determination of bactericidal and yeasticidal (*C. albicans*) activity in the qualitative suspension test (Method 8) (not for *M. terrae*, *M. avium*, *A. brasiliensis*, *C. difficile spores*).
2. The following tests are *obligatory*:
  - *Phase 2/Step 1*: Determination of bactericidal or yeasticidal (*C. albicans*) activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]) (for test conditions see **Table 1**). The test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* in the qualitative suspension test or if no qualitative suspension test was carried out), using a low and/or a high organic challenge and within the specified contact times (1 min, 5 min, 15 min, 30 min or 60 min) at 20 °C, by at least 5 lg levels as well as *C. albicans* by at least 4 lg levels.  
The optionally tested microorganisms *M. terrae*, *M. avium*, *A. brasiliensis* or *C. difficile spores* (Method 18) (DIN EN 14348 [4]), (DIN EN 13624 [3]), (DIN EN 17126 [5]) must be reduced by at least 4 lg levels.
  - *Phase 2/Step 2*: Determination of bactericidal and yeasticidal (*C. albicans*) activity under simulated-use conditions (Method 14.1 without mechanical action (DIN EN 17387) and Method 14.2 with mechanical action (DIN EN 16615) [1, 6, 7]).
    - Two series of tests must be run in each case.
    - Please refer to **Table 1** for the requirements to be met by this test procedure. The test product must reduce the number of the test organisms *S. aureus*, *E. hirae* and *P. aeruginosa*, using a low and/or high organic challenge and within the specified contact times (1 min, 5 min, 15 min, 30 min or 60 min) at 20 °C, by at least 5 lg levels as well as *C. albicans* by at least 4 lg levels.

➤ **As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*)**

- The optionally tested microorganisms *A. brasiliensis*, *M. terrae*, *M. avium* or *C. difficile* spores (Method 19) (DIN EN 17846) [8] must be reduced by at least 4 lg levels.

### Testing foams or sprays for mechanical application (wipe disinfection)

If one of the two following types of application is used, the suitability of the disinfection process must additionally be tested as part of a benchmark test:

1. The foam/spray is applied directly onto the surface and distributed immediately with a dry cloth.
2. The foam/spray is first applied onto a dry cloth and then distributed immediately over the surface with this cloth.

Details of the methodology can be found in the VAH communication published on 23 August 2021 [9].

**Table 1** Test parameters and required lg reduction for surface disinfectants in the quantitative suspension test and in simulate-use tests.

Area of application	Organic challenge	Contact times	Required lg reduction
Surface disinfection with and without mechanical action	<i>Low organic challenge</i> 0.03% albumin and/or	1 min 5 min 15 min	5 lg for bacteria (Exception: 4 lg for <i>P. aeruginosa</i> , 60 min <sup>1</sup> )
	<i>High organic challenge</i> 0.3% albumin and 0.3% sheep erythrocytes	30 min 60 min	4 lg for <i>C. albicans</i> (Exception: 3 lg for <i>C. albicans</i> 60 min <sup>1</sup> )  Optional: 4 lg for mycobacteria 4 lg for <i>A. brasiliensis</i> 4 lg for viruses 4 lg vor <i>C. difficile</i> spores

<sup>1</sup> This reduction is permitted in the simulated-use test, if the control values for *P. aeruginosa* due to dying are so low that the reduction by 5 lg levels or 4 lg levels for *C. albicans* cannot be shown.

### Efficacy against Fungi on Untreated Wood

The following *optional* test may be performed:

- Germ carrier test on untreated wood for determination of the fungicidal efficacy (Method P1 [1]).

When using the recommended concentration-time relations, there must not be any evidence of fungal growth.

### Listing virucidal properties

(For more detailed information, please also refer to the General Preface)

As announced in a VAH communication No. 3/2010 [10], the Disinfectants Commission decided to assess the virucidal properties of products on the basis of the test reports and expert opinions and include these in the VAH List, if requested by the companies (the applicant).

Details can be found in the VAH communication of 2018 [11] and in the requirements for VAH certification of virucidal activity [12].

The concentration-time relations for the activity spectrums *active against enveloped viruses*, *limited spectrum of virucidal activity*, *virucidal* or *virucidal activity PLUS* are listed in a separate line in the product entry. Regardless of the concentration-time relations specified in the expert opinions for the virucidal activity, the values listed for bactericidal and yeasticidal activity must be seen as minimum requirements for use. Therefore, the virucidal activity values specified in the VAH List are never lower than those for bactericidal and yeasticidal activity. Products claiming *active against enveloped viruses*, *limited spectrum of virucidal activity* and *virucidal* or *virucidal activity PLUS*

will have undergone a conformity assessment procedure conducted by independent experts of the Disinfectants Commission and based on two company-independent expert opinions (including the corresponding test reports) in accordance with the valid test methods [13-18]. The test reports and expert opinions must meet the VAH requirements for virucidal activity [12].

*The following tests are obligatory:*

Determination of virucidal activity (activity spectrum: *active against enveloped viruses, limited spectrum of virucidal activity, virucidal or virucidal activity PLUS*) in the quantitative suspension test [13–16] and under simulated-use conditions [17–19].

The test reports and expert opinions must meet the VAH requirements for virucidal activity [12].

- *Phase 2/Step 1:* Determination of virucidal activity (activity spectrum: limited spectrum of virucidal activity, limited spectrum of virucidal activity PLUS, virucidal activity and/or virucidal activity PLUS) in the quantitative suspension test (Method DVV/RKI 2005, 2008 or 2015 [13–15] or DIN EN 14476 [16]) at 20 °C as a concentrate (in addition to the concentrations required for assessment of the activity limit), using a low and/or high organic challenge at 1 min, 5 min, 15 min, 30 min or 60 min.

The test product must reduce the virus titre for the activity spectrum

- active against enveloped viruses: against vaccinia virus and, for oxidizing products, additionally against BVDV,
- limited spectrum of virucidal activity: against adenovirus and norovirus
- virucidal activity: against poliovirus, adenovirus, norovirus and SV40 virus
- virucidal activity PLUS against poliovirus, adenovirus, norovirus and SV40 virus

within the specified contact time(s) at 20 °C by at least 4 lg levels.

- *Phase 2/Step 2:* Determination of virucidal activity (activity spectrum: limited spectrum of virucidal activity and/or virucidal activity) in the simulated-use 4-field test [19].

The test product must reduce the virus titre for the activity spectrum

- active against enveloped viruses: against vaccinia virus
- limited spectrum of virucidal activity: against adenovirus and norovirus
- virucidal activity: against poliovirus, adenovirus, norovirus and SV40 virus
- virucidal activity PLUS against poliovirus, adenovirus, norovirus and SV40 virus

within the specified contact time(s) at 22 °C by at least 4 lg levels (for test details please refer to Chapter V2A of the Requirements and Methods for VAH Certification [12]).

## References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Kapitel 14.1 [Stand: April 2015], Kapitel 14.2 [Stand: Mai 2018]. Available: <https://vah-online.de/de/fuer-laboratorien> [Accessed 1.9.2025].
2. DIN EN 13727:2012+A2:2015. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13727:2012+A2:2015.
3. DIN EN 13624:2022-08. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1); German version EN 13624:2021.
4. DIN EN 14348:2005-04. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1); German version EN 14348:2005.
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## INSTRUMENT DISINFECTION (manual disinfection by immersion)

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### Introductory Remarks

The current test procedures for instrument disinfectants only refer to those which are used for immersion disinfection. All products listed for instrument disinfection have a minimum of bactericidal and yeasticidal activity (*C. albicans*) and meet the *Requirements and Methods for VAH Certification of Chemical Disinfection Procedures* [1].

The methodology described in the *Requirements and Methods* [1] complies with the European standards. For efficacy testing the results of quantitative suspension tests and of tests conducted under simulated-use conditions (contaminated frosted glass germ carriers as a model for medical devices) using a low and/or high organic challenge must be presented for the test organisms against which efficacy is claimed.

### Explanatory Notes on the Test Methodology

#### *Bacteria and Fungi*

1. The following *orientational* preliminary tests can be carried out to certify products for instrument disinfection:
  - Determination of bacteriostatic and yeasticidal activity as well as of suitable neutralizers (Method 7) (not for *M. terrae*, *M. avium*, *A. brasiliensis*).
  - Determination of bactericidal and yeasticidal activity in the qualitative suspension test (Method 8) (not for *M. terrae*, *M. avium*, *A. brasiliensis*).
2. The following tests are *obligatory*:
  - *Phase 2/Step 1*: Determination of bactericidal and yeasticidal activity in the quantitative suspension test (Method 9) (DIN EN 13727 [2], DIN EN 13624 [3]).

The test product must reduce the number of the test bacteria *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\*, *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* or if no qualitative suspension test was carried out), using a low and/or a high organic challenge and within the specified contact times (5 min, 15 min, 30 min or 60 min) at 20 °C, by at least 5 lg levels as well as *C. albicans* by at least 4 lg levels. The optionally tested microorganisms *M. terrae*, *M. avium* or *A. brasiliensis* (DIN EN 14348 [4], DIN EN 13624 [3]) must be reduced by at least 4 lg levels.
  - *Phase 2/Step 2*: Determination of bactericidal and yeasticidal activity under simulated-use conditions (Method 15) (DIN EN 14561 [5], DIN EN 14562 [6], DIN EN 14563 [7]).
    - Two series of tests must be run in each case.
    - Please see **Table 2** for the requirements to be met by this test procedure.

➤ *As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*)*

#### *Listing virucidal properties*

*(For more detailed information, please also refer to the General Preface)*

As announced in a VAH communication No. 3/2010 [8] the Disinfectants Commission decided to assess the virucidal properties of products on the basis of the test reports and expert opinions and include these in the VAH List, if requested by the companies (the applicant). Details can be found in the requirements for VAH certification of virucidal activity [9].

The concentration-time relations for *activity against enveloped viruses* or *virucidal activity* are listed in a separate line in the product entry. Regardless of the concentration-time relations specified for virucidal activity in the expert opinions, the values listed for bactericidal and yeasticidal activity must be seen as minimum requirements for use. Therefore, the values specified in the VAH List for virucidal activity are never lower than those for bactericidal and yeasticidal activity.

Products claiming *activity against enveloped viruses and/or virucidal activity* will have undergone a conformity assessment procedure conducted by independent experts of the Disinfectants Commission and based on two expert opinions (including the corresponding test reports) in accordance with the valid test methods [10-14] The test reports and expert opinions must meet the VAH requirements for virucidal activity [9].

The following tests are **obligatory**:

- **Phase 2/Step 1:** Determination of virucidal activity (activity spectrum: activity against enveloped viruses and/or virucidal activity) in the quantitative suspension test (Method DVV/RKI 2005, 2008 or 2015 [10-12] or DIN EN 14476 [13].

The test product must reduce the virus titre for the activity spectrum

- activity against enveloped viruses: vaccinia virus and, for oxidizing products, additionally against BVDV at 20 °C,
- virucidal activity at 20 °C bis < 40 °C: against poliovirus, adenovirus, norovirus and SV40 virus within the specified contact time(s),
- virucidal activity at ≥ 40 °C to ≤ 70 °C: against parvovirus within the specified contact time(s) by at least 4 lg levels.

- **Phase 2/Step 2:** Determination of virucidal activity (activity spectrum: limited spectrum of virucidal activity and/or virucidal activity) in the germ carrier test under simulated-use conditions DIN EN 17111 [14].

The test product must reduce the virus titre for the activity spectrum

- activity against enveloped viruses: activity against vaccinia virus at 20 °C,
- virucidal activity within the specified contact time(s) of between 20 °C and < 40 °C: against adenovirus, norovirus and SV40 virus,
- virucidal activity at between ≥ 40 °C and ≤ 70 °C: against parvovirus within the specified contact times(s) by at least 4 lg levels.

Two series of simulated-use tests must be run in each case:

- 1st test run: Two test surfaces per concentration–time relation, reference test, cytotoxicity test and virus control.
- 2nd test run: Two test surfaces per requested concentration–time relation, reference test, cytotoxicity test and virus control.

In the second test run for procedures carried out at < 40 °C, only the most resistant test virus from the first test run needs to be tested (for test details please refer to Chapter V3A of the Requirements and Methods for VAH Certification [1, 9]).

**Table 2** Test parameters and required lg reduction for instrument disinfectants in the quantitative suspension test an in simulate-use tests.

Area of application	Organic challenge	Contact times	Required lg reduction
<b>Instrument disinfection</b>	<i>Low organic challenge</i> 0.03% albumin and/or <i>High organic challenge</i> 0.3% albumin and 0.3% sheep erythrocytes	5 min 15 min 30 min 60 min	5 lg for bacteria 4 lg for <i>C. albicans</i>  Optional: 4 lg for mycobacteria 4 lg for <i>A. brasiliensis</i> 4 lg for viruses

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## TEXTILE DISINFECTION

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### Introductory Remarks

The VAH List of certified procedures for textile disinfection (in laundry processes) includes chemothermal single-chamber processes. In addition, chemical immersion disinfectant procedures may also be listed (see 1).

All processes  $\geq 60\text{ °C}$  have bactericidal, yeasticidal and tuberculocidal activity and were tested in quantitative suspension tests as well as in tests conducted under simulated-use conditions.

### Explanatory Notes on the Test Methodology

#### 1 Chemical laundry disinfection

##### Immersion procedure (Method 16)

A procedure was deemed effective if in the working dilution at  $13\text{ °C}$  the test organisms were inactivated on the test carriers within a maximum of 4–12 h [1].

### Explanatory Notes on the Test Methodology

#### 1 Chemothermal laundry disinfection (Method 17, with mechanical action in a washing machine)

##### Bacteria and Fungi

1. The following **orientational** preliminary tests can be carried out to certify processes at temperatures of between  $30\text{ °C}$  and  $< 60\text{ °C}$ 
  - Determination of bacteriostatic and yeastistatic (*C. albicans*) activity as well as of suitable neutralizers (Method 7) (not for *M. terrae*, *M. avium*, *A. brasiliensis*).
  - Determination of bactericidal and yeasticidal (*C. albicans*) activity in the qualitative suspension test (Method 8) (not for *M. terrae*, *M. avium*, *A. brasiliensis*).
2. The following tests are **obligatory** for processes between  $30\text{ °C}$  and  $< 60\text{ °C}$ :
  - **Phase 2/Step 1:** Determination of bactericidal and yeasticidal activity in the quantitative suspension test (Method 9 [1]) (DIN EN 13727 [2], DIN EN 13624 [3]).  
Using a low (procedures **with prewash**) or a high organic challenge (procedures **without prewash**), the test product must reduce the number of the test organisms *S. aureus*, *E. hirae*, *P. aeruginosa*, *P. mirabilis*\* and *E. coli*\* (\*if this had proved to be more resistant than *P. aeruginosa* or if no qualitative suspension test was carried out), within the specified contact times (10 min, 15 min or 20 min) and at the process temperature, by at least 5 lg levels as well as *C. albicans* by at least 4 lg levels. The optionally tested microorganisms *M. terrae*, *M. avium* and *A. brasiliensis* (Method 9) (DIN EN 14348 [4], DIN EN 13624 [3]) must be reduced by at least 4 lg levels.
  - **Phase 2/Step 2:** Testing textile disinfection processes at temperatures of between  $30\text{ °C}$  and  $< 60\text{ °C}$  (Method 17.1) (DIN EN 16616) [1, 5].  
A chemothermal textile disinfection procedure (single-chamber process) is deemed effective if, at the recommended concentration, contact time and temperature as well as the prescribed liquor ratio, it reduces the number of the test organisms *S. aureus*, *E. hirae*, *E. coli* and *P. aeruginosa* on the germ carriers by more than 7 lg levels and *C. albicans* by more than 6 lg levels (*A. brasiliensis* (optional), 6 lg levels, and *M. terrae* or *M. avium* (optional), 7 lg levels). Furthermore, no test organisms should be detected in 100 ml cleaning solution after the disinfection phase.

➤ **As such, each product certified and listed has demonstrated efficacy against bacteria and yeasts (*C. albicans*)**

3. *The following tests are **obligatory** for processes of between  $\geq 60$  °C and 70 °C*
- *Phase 2/Step 1: Determination of bactericidal activity in the quantitative suspension test at the process temperature (Method 9).*  
The test product must reduce the colony count of the test bacterium *E. faecium* under a low (processes *with prewash*) or a high organic challenge (processes *without prewash*) within the specified contact times (10 min, 15 min or 20 min) at the process temperature by at least 5 lg levels.
  - *Phase 2/Step 2: Testing textile disinfection process at temperatures of between  $\geq 60$  °C and 70 °C (Method 17.2).*  
A chemothermal textile disinfection procedure (single-chamber process) is deemed effective if, at the recommended dosage, contact time and temperature as well as at the prescribed liquor ratio, it reduces *E. faecium* on the germ carriers by more than 7 lg levels within the specified time. Furthermore, no test organisms should be detected in 100 ml cleaning solution after the disinfection phase.
- **As a result of the thermal resistance of *E. faecium* each product listed for disinfection procedures between  $\geq 60$  °C and 70 °C has demonstrated efficacy against bacteria and yeasts (*C. albicans*), mycobacteria, *M. tuberculosis* and fungi.**

### *Listing virucidal properties*

*(For more detailed information, please also refer to the General Preface)*

As announced in a VAH communication No. 3/2010 [6] the Disinfectants Commission decided to assess the virucidal properties of products on the basis of the test reports and expert opinions and include these in the VAH List, if requested by the companies (the applicant). Textile disinfection processes with virucidal properties are clearly indicated. For textile disinfection *virucidal activity* may be claimed.

The concentration-time relations for *virucidal activity* are listed in a separate line in the product entry. Regardless of the concentration-time relations, the values needed for bactericidal and yeasticidal activity must be seen as minimum requirements for use. Therefore, the values specified in the VAH List for virucidal activity are never lower than those for bactericidal and yeasticidal activity. Products claiming *virucidal activity* will have undergone a conformity assessment procedure conducted by independent experts of the Disinfectants Commission. The test reports and expert opinions must meet the VAH requirements for virucidal activity [7].

*The following tests are **obligatory**:*

- *Phase 2/Step 1: Determination of virucidal activity (activity spectrum *virucidal activity* in the quantitative suspension test according to DIN EN 14476 [8]). To that effect, the entire procedure (i.e. all process parameters in one test) must be tested at  $20$  °C  $\pm$  1 °C and at the intended process temperature. The virus titres must also be determined at  $20$  °C  $\pm$  1 °C and at the intended process temperature. Moreover, a test with peracetic acid as reference must be performed, or, alternatively, tests according to DVV/RKI 2008, chapters 5.1 and 7.7 [9] may be accepted as proof of the quality of the test viruses (control with pH value of the laundry process at 20 °C and process temperature).*  
The test product must reduce the virus titre of parvovirus for the activity spectrum *virucidal activity* under the specified conditions, within the specified contact times(s) and at the test temperature by at least 4 lg levels (for test details please refer to Annex V4 of the Requirements and Methods for VAH Certification [1]).

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