HARTMANN

Helps. Cares. Protects.

# European Standards

## Efficacy and Contact Time of Disinfectants



# Table of Contents


European Standards for Disinfectants ..... 4

Two Steps to Effectiveness ..... 5

A Question of Efficacy ..... 6

Test Organisms by Spectrum of Activity ..... 8

The Most Important Standards in Detail ..... 9

Phase 2 / Step 1

EN 13727 Bactericidal ..... 9

EN 13624 Yeasticidal / Fungicidal ..... 9

EN 14476 Virucidal ..... 9

Phase 2 / Step 2

EN 1500 Hygienic Hand Disinfection ..... 10

EN 17430 Virucidal Hygienic Hand Disinfection ..... 10

EN 12791 Surgical Hand Disinfection ..... 11

EN 16615 Bactericidal, Yeasticidal / Fungicidal and Tuberculocidal / Mycobactericidal Surface Disinfection ..... 12

Efficacy Claims ..... 13

National Evaluation Systems: Example Germany ..... 15


# European Standards for Testing the Efficacy of Disinfectants

## Uniform Standards

The European Committee for Standardization (CEN) develops and adopts uniform standards that define the requirements of European countries for disinfectants used in medicine, food production, industry, and veterinary medicine. All CEN member states may send national experts to the respective European standardization committees and are thus actively involved in the development and updating of European Standards (EN). The subsequent voting is weighted according to the population of each member state. The standardization of ENs harmonizes the national testing methods of the individual member states.

This enables the comparability of disinfectants' efficacy on a pan-European level. Testing in accordance with European standards is decisive for assessing the efficacy of disinfectants and, consequently, for regulatory evaluation and approval.

## The Standard of Standards: EN 14885

The European standards are subject to regular revisions. They are continuously updated in accordance with the latest scientific findings. As an overarching standard, EN 14885 defines the application of all European standards for the respective areas of use of chemical disinfectants and antiseptics. The aim of the standard is to illustrate the interplay between the individual standards and to define the resulting possibilities for claims and recommendations for use.

SCIENCE CENTER HARTMANN

Research for infection protection

At a Glance:

# European Standards for Disinfectants

| Test Level | Spectrum of Activity | Hands: Hygienic Hand Disinfection | Hands: Surgical Hand Disinfection | Surfaces: With Mechanical Action |
|---|---|---|---|---|
| **Phase 1** Basic Test – Quantitative Suspension Test | **Bactericidal** | EN 1040 | EN 1040 | EN 1040 |
| | **Yeasticidal** | EN 1275 | EN 1275 | EN 1275 |
| | **Fungicidal** | EN 1275 | EN 1275 | EN 1275 |
| | **Mycobactericidal / Tuberculocidal** | x | x | x |
| | **Virucidal** | x | x | x |
| | **Sporicidal** | EN 14347 | EN 14347 | EN 14347 |
| **Phase 2 / Step 1** Suspension Test with Organic Load | **Bactericidal** | EN 13727 | EN 13727 | EN 13727 |
| | **Yeasticidal** | EN 13624 | EN 13624 | EN 13624 |
| | **Fungicidal** | x | x | EN 13624 |
| | **Mycobactericidal / Tuberculocidal** | EN 14348 | x | EN 14348 |
| | **Virucidal** | EN 14476 | x | EN 14476 |
| | **Sporicidal** | x | x | EN 17126 |
| **Phase 2 / Step 2** Quantitative Carrier Test | **Bactericidal** | EN 1500 | EN 12791 | EN 16615 |
| | **Yeasticidal** | x | x | EN 16615 |
| | **Fungicidal** | x | x | EN 16615 |
| | **Mycobactericidal / Tuberculocidal** | x | x | EN 16615 |
| | **Virucidal** | EN 17430 | x | x |
| | **Sporicidal** | x | x | EN 17846 |

What's Behind It

# Two Steps to Effectiveness

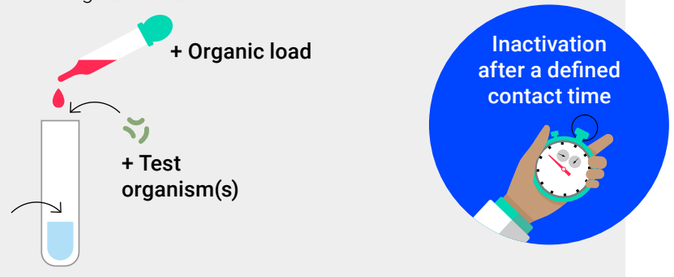
Efficacy tests for chemical disinfectants are divided into two phases, each with its own steps.

*If a product is being tested in Phase 2, no tests from the Phase 1 efficacy testing stage need to be conducted.*

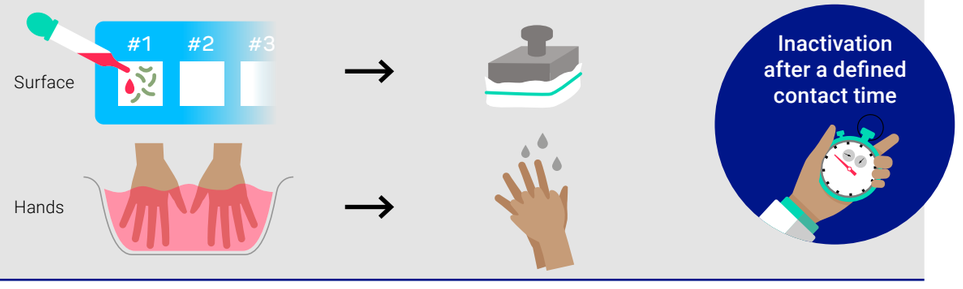
**Phase 1 tests** are primarily conducted as part of product development and cannot be used to support product claims. These basic tests are designed to determine whether active ingredients or formulations are fundamentally effective.




**Phase 2, Step 1 tests** are quantitative suspension tests in which the efficacy of the disinfectant is additionally evaluated under conditions of organic load.




**Phase 2, Step 2 tests** are quantitative carrier tests in which the product's efficacy is evaluated directly on the relevant surface under conditions that simulate real-world use.




*Figures: Test model in accordance with EN 14885*

Lab-based

Practice-oriented

Bacteria, Viruses, and More

# A Question of Efficacy

Disinfectants can inactivate a wide variety of pathogens. However, it is important to note that not all disinfectants are equally effective. A disinfectant with limited virucidal activity is not automatically effective against all viruses. And a tuberculocidal disinfectant is not necessarily effective against all mycobacteria.

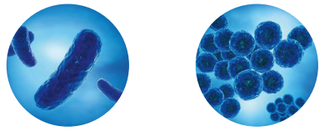
To ensure that the disinfectant you are using is effective against the specific pathogen you are targeting, it is worth taking a look at the various spectra of activity.

*To be approved for use in the medical field, disinfectants must, as a minimum requirement, demonstrate bactericidal and yeasticidal efficacy.*

## Bactericidal activity

Bacteria are among the most common causes of healthcare-associated infections in hospitals and also play a significant role in everyday life. Bactericidal disinfectants are used to prevent their spread.

**Good to know:** The bactericidal effectiveness also extends to multidrug-resistant bacteria. However, bacterial spores are not necessarily eliminated by this method and require special sporicidal disinfectants!



*e.g., Gram-negative, Gram-positive, antibiotic-resistant bacteria, Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella spp.*

## Sporicidal Activity

Bacterial spores are particularly resilient dormant forms of certain bacteria. Due to their high survivability, they pose special challenges for disinfection. Sporicidal disinfectants are used to inactivate them.

**Good to know:** In human medicine, sporicidal efficacy is demonstrated either specifically against *Clostridioides difficile* or generally against bacterial spores!



***Sporicidal against C. diff.***
*Clostridioides difficile*

***Sporicidal***
*e.g., Bacillus anthracis, Clostridium chauvoei*

## Mycobactericidal / Tuberculocidal Activity

Mycobacteria possess a particularly robust cell wall and are therefore more difficult to inactivate than many other bacteria. To ensure reliable microbial inactivation, disinfectants are tested for their mycobactericidal or tuberculocidal activity.

**Good to know:** A disinfectant with mycobactericidal activity also covers the tuberculocidal spectrum!



***Tuberculocidal***
*Mycobacterium tuberculosis*

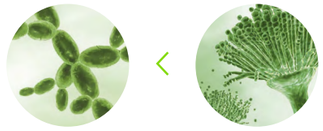
***Mycobactericidal***
*Mycobacterium spp.*

## Yeasticidal / Fungicidal Activity

Although yeasts are biologically classified as fungi, infection prevention distinguish between yeasticidal and fungicidal activity. The reason: they differ in their survival strategies and, consequently, in their susceptibility to disinfection measures.

While yeasts reproduce by budding, moulds (filamentous fungi) reproduce by means of resistant spores that can survive for extended periods, even under unfavorable conditions. Therefore, a fungicidal disinfectant is required when mould contamination is a concern.

**Good to know:** A disinfectant with fungicidal activity is also effective against yeasts and therefore automatically covers the yeasticidal spectrum!



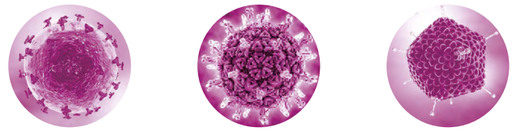
***Yeasticidal***
*Yeasts*
*e.g., Candida albicans, Candida glabrata, Candidozyma auris, Cryptococcus spp.*

***Fungicidal***
*Other fungi*
*e.g., Aspergillus spp., Microsporum canis*

## Virucidal Activity

Since viruses cannot replicate on their own but depend on host cells, virucidal disinfectants are said to inactivate rather than kill viruses.

**Good to know:** Not all virucidal disinfectants are effective against every virus. Their efficacy depends on the structure of the virus! Therefore, virucidal activity is classified into three levels:



***Virucidal Activity Against Enveloped Viruses***
*Level 1:*
All enveloped viruses
e.g., influenza viruses, herpesviruses, HIV

***Limited-Spectrum Virucidal Activity***
*Level 2:*
*All enveloped viruses + 3 non-enveloped viruses*
*Non-enveloped viruses:*
*adenoviruses, rotaviruses, noroviruses*

***Virucidal***
*Level 3*
All enveloped and non-enveloped viruses
e.g., polioviruses, rhinoviruses, hepatitis A virus (HAV)

At a Glance

# Test Organisms by Spectrum of Activity

The effectiveness of disinfectants is tested using specified test microorganisms defined in the EN. Each of these represents a specific spectrum of activity. If the test microorganisms are inactivated, this also applies to all other microorganisms within that spectrum.

For hand sanitizers, the selection of test pathogens in Phase 2, Step 2 is particularly important, as testing is conducted directly on the skin of test subjects. Therefore, the pathogens used must not be harmful to humans (human pathogens).

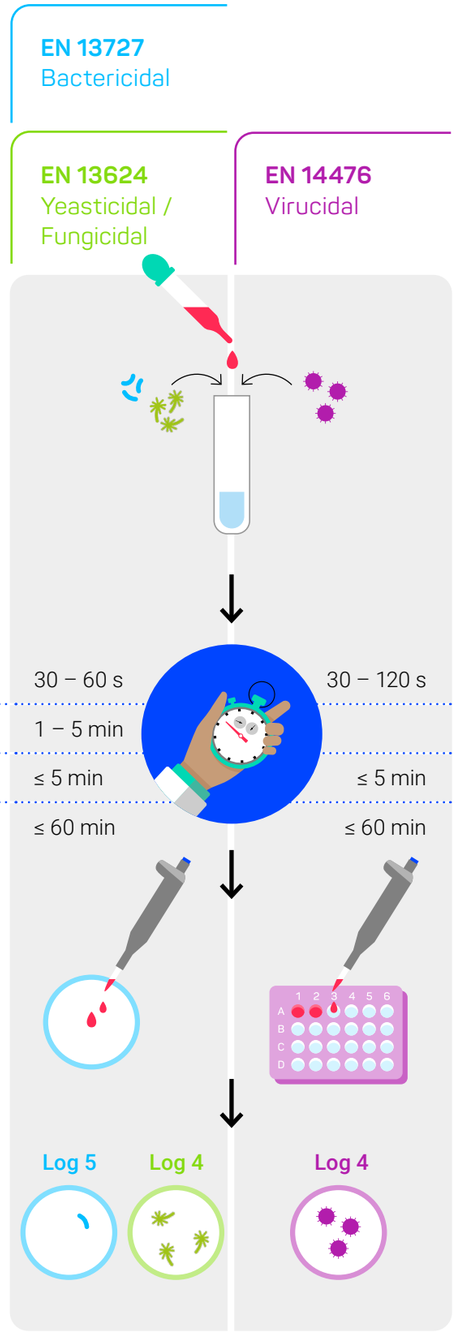
| | Test Organisms |
|---|---|
| **Bactericial** | • *Pseudomonas aeruginosa*<br>• *Enterococcus hirae*<br>• *Escherichia coli*<br>• *Enterococcus faecium* |
| **Sporicidal against *C. difficile*** | • *Clostridioides difficile* spores |
| **Sporicidal** | • *Bacillus cereus* spores<br>• *Bacillus subtilis* spores |
| **Tuberculocidal** | • *Mycobacterium terrae* |
| **Mycobactericidal** | • plus *Mycobacterium avium* |
| **Yeasticidal** | • *Candida albicans* |
| **Fungicidal** | • plus *Aspergillus brasiliensis* |
| **Virucidal Activity Against Enveloped Viruses** | • Vacciniavirus |
| **Limited-Spectrum Virucidal Activity** | • Murine norovirus<br>• Adenovirus |
| **Virucidal** | • plus Poliovirus |



The Method Behind the Number

# The Most Important Standards in Detail

## Phase 2 / Step 1




The test organisms are mixed in a test tube together with an organic load (protein and, where applicable, blood) and the disinfectant.

The organic load simulates soiling encountered in healthcare settings.

The test mixture is incubated for a period specified in the standard.

| | | |
|---|---|---|
| **Hand disinfection** | Hygienic | 30 – 60 s |
| | Surgical | 1 – 5 min |
| **Surface disinfection** | Patient-near | ≤ 5 min |
| | Patient-far | ≤ 60 min |

Subsequently, a portion of the test mixture is cultured in petri dishes. Only microorganisms that have not been inactivated by the disinfectant will grow.

Finally, the surviving microorganisms are counted and compared with the initial microbial count. An effective disinfectant must inactivate a specified number of microorganisms.

**Good to know:** Log reduction indicates the extent to which a disinfectant reduces the number of pathogens!
A Log 4 reduction corresponds to a 99.99% reduction, while a Log 5 reduction corresponds to a 99.999% reduction.

## Phase 2 / Step 2

*In addition to hygienic hand disinfection, virucidal hygienic hand disinfection has been a separate test method since 2024. It requires the efficacy claims "limited-spectrum virucidal activity" or "virucidal".*

**EN 1500**
Hygienic Hand Disinfection

**EN 17430**
Virucidal Hygienic Hand Disinfection

The hands are artificially **contaminated** with the test organism.

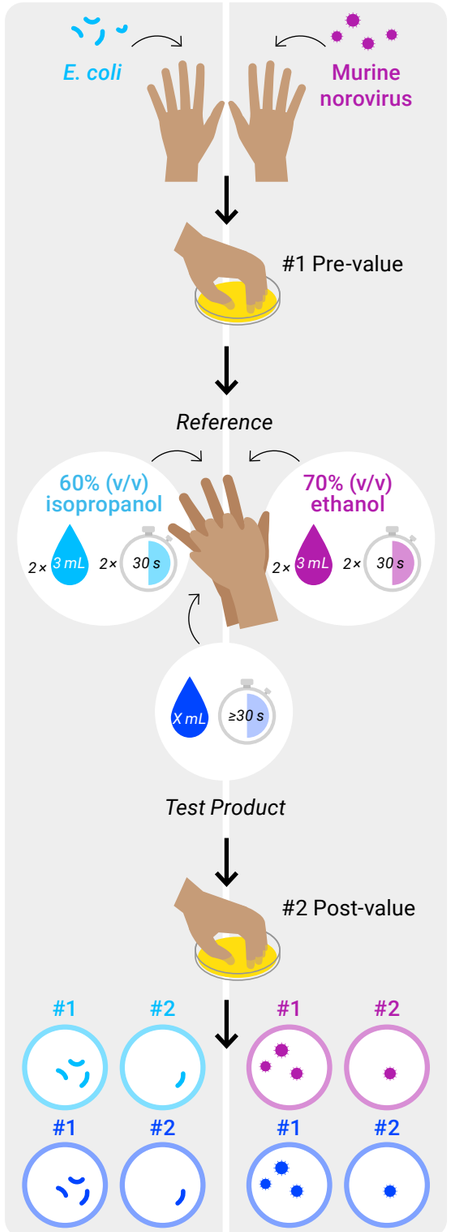
After drying, the hands are rinsed in a Petri dish containing a recovery medium. This is used to determine the **number of microorganisms** present on the hands **before disinfection** (pre-value).

*Reference*
The hands are then disinfected with 2 × 3 mL of the reference product for 2 × 30 s. A standardized rubbing technique is used.

*Test Product*
The hands are disinfected with the **amount of disinfectant specified by the manufacturer** for 30 to 60 s. The standardized rubbing technique is also used here.

After disinfection, the hands are rinsed again in the recovery medium. This is used to determine **how many microorganisms** remain on the hands **after disinfection** (post-value).

For both the reference product and the test product, the **logarithmic reduction** is calculated from the difference between the pre-value and the post-value. An effective disinfectant **must not be statistically inferior** to the reference product.






## Phase 2 / Step 2

*Surgical hand disinfection reduces not only microorganisms that are temporarily present on the hands (transient skin flora), but also the microorganisms that naturally inhabit the skin (resident skin flora). Therefore, the number of microorganisms on the hands is additionally determined three hours after disinfection.*

**EN 12791**
Surgical Hand Disinfection

At the beginning of the test, the hands are washed **with soap.**

After drying, the hands are rubbed in a Petri dish containing a recovery medium. This procedure is used to determine the **number of microorganisms** present on the hands **before disinfection** (pre-value).

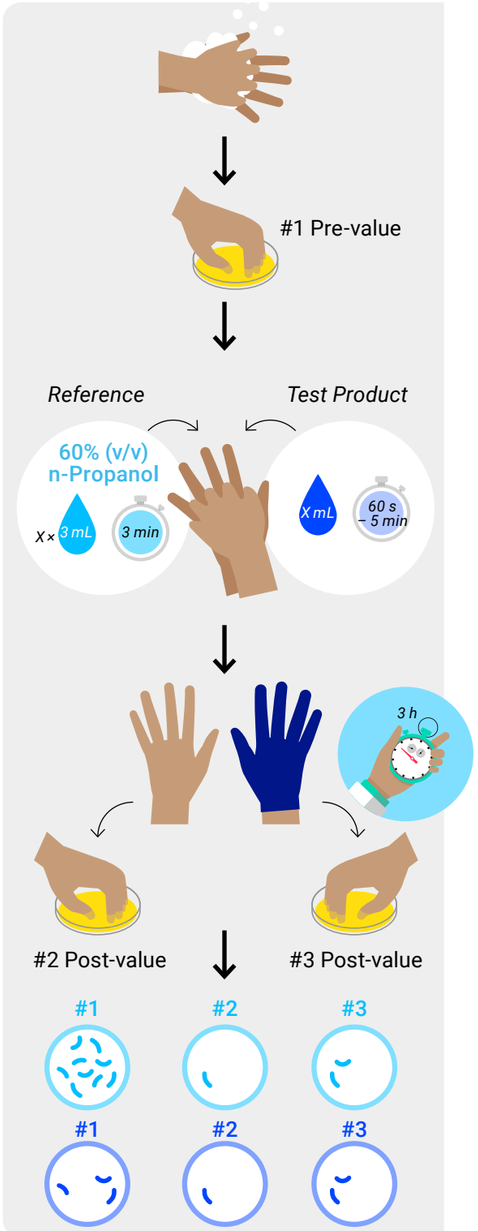
*Reference*
The hands are rubbed according to a standardized procedure. As soon as the hands begin to dry, additional 3 mL portions are applied and distributed over the hands so that they remain moist throughout the entire **3-min contact time.**

*Test Product*
The hands are disinfected using the **volume and application frequency specified by the manufacturer** for a contact time of 60 s to 5 min. The standardized hand-rubbing technique is also used in this case.

After disinfection and drying, a glove is placed on one hand and worn for 3 h. In addition to the immediate effect of the disinfectant, its **sustained efficacy over time** is therefore also assessed.

After disinfection, the hands are again rubbed in a recovery medium. This is used to determine **how many microorganisms** remain on the hands immediately **after disinfection** (post-value 1) and after 3 h (post-value 2).

For both the reference product and the test product, the **logarithmic reduction** is calculated from the difference between the pre-value and the post-value, both for the immediate effect and for the assessment 3 h after disinfection. An effective disinfectant **must not be statistically inferior** to the reference product.



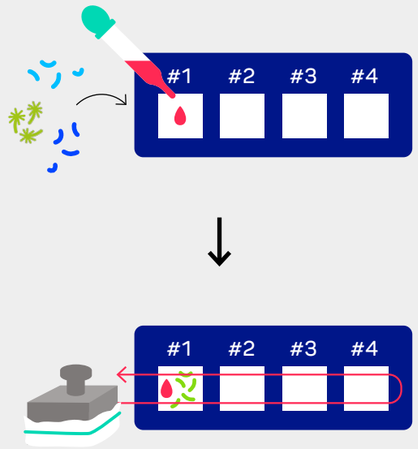
## Phase 2 / Step 2

**EN 16615**
Bactericidal Surface Disinfection

**EN 16615**
Yeasticidal/Fungicidal Surface Disinfection

EN 16615
Mycobactericidal/Tuberculocidal Surface Disinfection

Four consecutive test fields (each 5 x 5 cm) are marked on a test surface. **The first test field** is contaminated with the test pathogen and an organic load (protein and, if applicable, blood). The organic load simulates **contamination of a surface in a healthcare setting.**

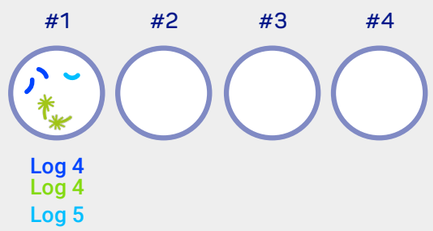



The four test fields are disinfected using the test product. For this purpose, either a standardized wipe impregnated with the test product or a ready-to-use wipe is used. The wipe, weighted with a standard load, is moved across the test surface according to a **defined wiping pattern**, starting with test field 1.




After the defined contact time, the test areas are sampled with moist cotton swabs to **detect any remaining microorganisms.**

The contact time is specified in the standard, with a distinction made between surfaces in close proximity to patients and surfaces located farther away from patients.




Finally, the number of microorganisms on each test field is counted and compared with the initial microbial count.

An effective disinfectant must inactivate a specified number of microorganisms on the first test field, and the microbial count on test field 2–4 must be **≤ 50 colony-forming units (CFU).**



From Testing to Product

# Efficacy Claims

*How is efficacy indicated on a disinfectant product? A look at the label of a surface disinfectant provides all the key information on its spectrum of activity, the underlying test standards, and the required contact time.*

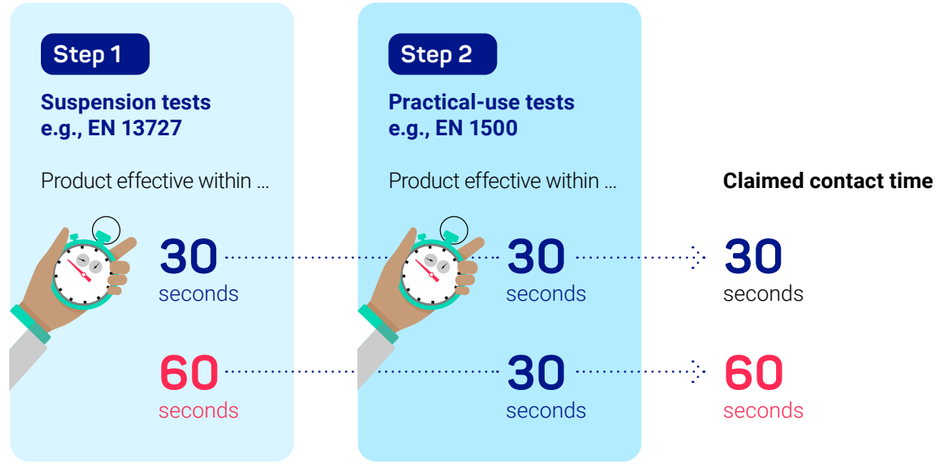


**Efficacy Claims (high organic load)**

| | | |
|---|---|---|
| Bactericidal / Yeasticidal | EN 13727 / EN 13624 / EN 16615 | 2 min |
| Tuberculocidal / Mycobactericidal | EN 14348 / EN 16615 | 60 min |
| Virucidal Activity Against Enveloped Viruses | EN 14476 | 2 min |
| Limited-Spectrum Virucidal Activity | EN 14476 | 2 min |
| Virucidal | EN 14476 | 2 min |

This surface disinfectant offers a particularly broad spectrum of efficacy, providing reliable effectiveness against microorganisms relevant in everyday practice. Testing in accordance with EN requirements ensures a robust and practice-oriented assessment of disinfectant performance.

The efficacy claims of a product are based on the results of both test steps of Phase 2. Both suspension tests (Phase 2, Step 1) and practical-use tests simulating real-life conditions (Phase 2, Step 2) are taken into account. If the two test steps result in different effective contact times, the longer contact time applies to the product's efficacy claim.



Excursion

# National Evaluation Systems: Example Germany

## Why do efficacy tables list VAH approvals in addition to the European standards?

*In addition to European standards, specific national test methods exist in Germany. Both EN methods and VAH methods include quantitative suspension tests as well as practical-use test procedures for evaluating the efficacy of disinfectants.*



## VAH – Association for Applied Hygiene

The VAH publishes a list of disinfectants for use in human medicine in Germany. The VAH listing is a national assessment system used alongside EN methods.

For routine use in human medicine, efficacy against vegetative bacteria and yeasts must be demonstrated according to both EN and VAH methods. Products that successfully meet the requirements are granted a certificate and included in the VAH disinfectants list.

Certification is valid for three years and must be renewed thereafter.

## RKI – Robert Koch-Institute

The RKI is Germany's central government institution responsible for the surveillance and prevention of infectious diseases. In addition to its epidemiological role, the RKI publishes its own list of disinfectants (the RKI-List). This list is the authoritative reference for officially mandated decontamination measures in accordance with Section 18 of the German Infection Protection Act (IfSG), for example during outbreaks of notifiable infectious diseases.

Disinfectants listed by the RKI meet the specific requirements that may arise in outbreak situations, such as higher microbial burdens or unusual levels of contamination. As a result, higher concentrations and/or longer contact times may be required.

**The RKI Disinfectants List differentiates efficacy according to the following activity areas:**

| | |
|---|---|
| Activity Area A | Vegetative bacteria (including mycobacteria), as well as yeasts and moulds |
| Activity Area B | Viruses (enveloped and non-enveloped) |
| Activity Area C | Spores of the anthrax pathogen |
| Activity Area D | Spores of the pathogens causing gas gangrene and tetanus |

Research for infection protection

## References


[1] Deutsches Institut für Normung e. V., European Standards. Available at: https://www.din.de/de/din-und-seine-partner/din-in-der-welt/din-in-europa/europaeische-normen (accessed 01. July 2026).

[2] DIN EN 14885:2022 + AC:2023 Chemical Disinfectants and Antiseptics – Application of European Standards for Chemical Disinfectants and Antiseptics; 2023.

[3] DIN EN 13727:2015-12. 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), 2015.

[4] 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), 2022.

[5] 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), 2025.

[6] DIN EN 1500:2017-10. Chemical Disinfectants and Antiseptics – Hygienic Hand Rub – Test Method and Requirements (Phase 2, Step 2), 2017.

[7] DIN EN 17430:2024-05. Chemical Disinfectants and Antiseptics – Virucidal Hygienic Hand Rub – Test Method and Requirements (Phase 2, Step 2), 2024.

[8] DIN EN 12791:2018-01. Chemical Disinfectants and Antiseptics – Surgical Hand Rubs – Test Method and Requirements (Phase 2, Step 2), 2018.

[9] DIN EN 16615:2026-06. Chemical Disinfectants and Antiseptics – Quantitative Test Method for the Evaluation of Bactericidal, Yeasticidal and/or Fungicidal and/or Tuberculocidal and/or Mycobactericidal Activity on Non-Porous Surfaces with Mechanical Action Employing Wipes or Mops in the Medical Area (4-Field Test) – Test Method and Requirements (Phase 2, Step 2), 2026.


HARTMANN

Helps. Cares. Protects.


PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim
Germany

Phone: +49-7321-36-0
Fax: +49-7321-36-3636
info@hartmann.info
www.hartmann.info