

## Overview of proofs of efficacy to be submitted according to the area of application

Efficacy assessments must be conducted according to recognised standards by competent labs (bacteriology, virology etc.) with an appropriate quality assurance system. Full copies of the reports must be submitted to us. The test reports must contain all the information necessary to interpret the results. All test and control data must be described and listed. Reports must be signed by the scientist responsible, and the identity of the formulation tested must be confirmed. Before a report can be accepted, we must make sure that the tests were conducted with a product-identical formulation. Accordingly, the active substances in the tested solution and their concentrations should be clearly stated in the reports\*. In cases of doubt, the office may demand the raw data and a random sample for analysis. For a disinfectant to be authorised, at least efficacy against bacteria and yeast must be demonstrated.

\* If the reports do not include this information, we will ask for the manufacturing records with the complete formulas of all tested batches. Otherwise, the reports will be rejected.

Application area (1)	Organisms	Quantitative suspension test (phase 2 / step 1)	Test simulating practical conditions (phase 2 / step 2)
<b>Surface disinfection</b> (If the product is marketed as a detergent offering simultaneous disinfection, it must be tested with a high level of organic soiling (= dirty conditions).)	Bacteria (and mycobacteria)	EN 1276 or EN 13727 (and EN 14348)	EN 13697
	Yeast / Fungi	EN 1650 or EN 13624	EN 13697
	Spores (bacteria)	EN 13704 or EN 17126	/
	Viruses (see page 2)	EN 14476 or DVV Possibly EN13610 (bacteriophages)	/
	Airborne room disinfection (by automated process) ≠ air disinfection	Ditto (bactericidal, fungicidal, virucidal, etc.)	AFNOR NF T72-281 or EN 17272 (bactericidal, fungicidal, virucidal, etc. according to claims)
	With wipes	Ditto (bactericidal, fungicidal, virucidal, etc.)	EN 16615
<b>Instrument disinfection</b>	Bacteria (and mycobacteria)	EN 13727 (and EN 14348)	EN 14561 (and EN 14563)
	Yeast / Fungi	EN 13624	EN 14562
	Spores (bacteria)	EN 13704 or EN 17126	/
	Viruses	EN 14476 or DVV	/
<b>Hygienic hand disinfection</b> (clean conditions) <i>versus</i> <b>Hygienic hand washing</b> (dirty conditions)	Bacteria	EN 1276 or EN 13727	Hygienic hand disinfection: EN 1500 Hygienic hand washing: EN 1499
	Yeast / Fungi	EN 1650 or EN 13624	/
	Viruses	EN 14476 or DVV	/
<b>Surgical hand disinfection</b>	Bacteria	EN 1276 or EN 13727	EN 12791
	Fungi	EN 1650 or EN 13624	/
	Viruses	EN 14476 or DVV	/

Subsequent changes must not be made to test reports. Any corrections, amendments or deletions must be entered in a supplement to the report in which the changes made and the date and reasons for these changes are specified.

(1) In those few cases where the standard tests are not at all appropriate for the process and the intended use, ad hoc tests are permitted. However, the efficacy requirements must be comparable to the requirements in the standards.

### Virucidal activity

Viruses represent a special case. They exist in a wide variety of forms, and laboratory culture methods can sometimes prove difficult to perform. A CEN standard with a suspension test exists for viruses and is required. Tests simulating practical conditions are also existing but are not required for A<sub>N</sub>.

In Switzerland, a disinfectant may be described as "virucidal" only if it has been successfully tested against several virus types. The term "virucidal activity" indicates general efficacy against viruses. Rare viruses can be more resistant than those that are tested. We have adopted the list of viruses set out in standard EN14476. For some years this standard has specified three levels reflecting the sensitivity of the viruses: "*virucidal activity against enveloped viruses*", "*limited spectrum virucidal activity*" and "*virucidal activity*".

The claim "*virucidal activity*" indicates general efficacy against viruses.

The claim "*limited spectrum virucidal activity*" means that the product is effective against enveloped viruses (see EN14476, Annex A) and against the adenovirus, norovirus and rotavirus.

The claim "*enveloped viruses*" indicates activity against all enveloped viruses.

	<b><i>Virucidal activity against enveloped viruses</i></b>	<b><i>Limited spectrum virucidal activity</i></b>	<b><i>Virucidal activity</i></b>
At least tested viruses (hands, surfaces, instruments)	Vaccinia virus	Adenovirus Murine norovirus	Poliovirus Adenovirus Murine norovirus
Additional claim	Each additional enveloped virus *	Each additional enveloped or non-enveloped virus *	Each additional enveloped or non-enveloped virus *

\* If another virus is listed on the label in addition to the general claim – for example "*active against enveloped viruses*" – appropriate test results for this other virus should exist.

#### References

Standard EN 14476 "*Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1)*"

Prüfung und Deklaration der Wirksamkeit von Desinfektionsmitteln gegen Viren. Bundesgesundheitsblatt Gesundheitsforschung und Gesundheitsschutz 2004. Bd 47:62-66

"*Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten e.V. und des Robert Koch-Institutes zur Prüfung von Chemischen Desinfektionsmittel auf Wirksamkeit gegen Viren in der humanmedizin*". Hyg. Medizin 2008. 33: 315-322.



### Addendum for PT3 disinfectants for the control of epizootic diseases (Epizootic Diseases Act, SR 916.40)

<b>Application area</b>	<b>Organisms</b>	<b>Quantitative suspension test (phase 2 / step 1)</b>	<b>Test simulating practical conditions (phase 2 / step 2)</b>
Surface disinfection, veterinary use; low-level contamination (epizootic diseases)	Bacteria	EN 1656 low-level soiling	EN 14349 low-level soiling of non-porous surfaces
	Fungi	EN 1657 low-level soiling	EN 16438 low-level soiling of non-porous surfaces
	Yeasts	EN 1657 low-level soiling	EN 16438 low-level soiling of non-porous surfaces
	Mycobacteria	EN 14204 low-level soiling	
	Viruses	EN 14675 low-level soiling	
	Spores	EN 13704 low-level soiling	
Surface disinfection, veterinary use; high-level contamination (epizootic diseases)	Bacteria	EN 1656 high-level soiling	EN 14349 high-level soiling of non-porous surfaces
	Fungi	EN 1657 high-level soiling	EN 16438 high-level soiling of non-porous surfaces
	Yeasts	EN 1656 high-level soiling	EN 16438 high-level soiling of non-porous surfaces
	Mycobacteria	EN 14204 high-level soiling	
	Viruses	EN 14675 high-level soiling	
	Spores	EN 13704 high-level soiling	
Immersion of contaminated objects, veterinary use (epizootic diseases)	Bacteria	EN 1656 high-level soiling	EN 14349 high-level soiling of non-porous surfaces
	Fungi	EN 1657 high-level soiling	EN 16438 high-level soiling of non-porous surfaces
	Yeasts	EN 1657 high-level soiling	EN 16438 high-level soiling of non-porous surfaces
	Mycobacteria	EN 14204 high-level soiling	
	Viruses	EN 14675 high-level soiling	
	Spores	EN 13704 high-level soiling	