

Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 17387:2021 sisaldab Euroopa standardi EN 17387:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 17387:2021 consists of the English text of the European standard EN 17387:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.08.2021.	Date of Availability of the European standard is 18.08.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.20, 71.100.35

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Chemical disinfectants and antiseptics - Quantitative test
for the evaluation of bactericidal and yeasticidal and/or
fungicidal activity of chemical disinfectants in the medical
area on non-porous surfaces without mechanical action -
Test method and requirements (phase 2, step 2)**

Antiseptiques et désinfectants chimiques - Essai
quantitatif pour l'évaluation de l'activité bactéricide et
levuricide et/ou fongicide des désinfectants chimiques
utilisés en médecine sur des surfaces non poreuses
sans action mécanique - Méthode d'essai et exigences
(phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika -
Quantitativer Versuch zur Bestimmung der
bakteriziden und levuroziden und/oder fungiziden
Wirkung chemischer Desinfektionsmittel im
humanmedizinischen Bereich auf nicht porösen
Oberflächen ohne mechanische Einwirkung -
Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 25 January 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword.....	3
Introduction	4
1 Scope.....	5
2 Normative references.....	5
3 Terms, definitions and abbreviations	5
3.1 Terms and definitions	5
3.2 Symbols and abbreviations	6
4 Requirements.....	6
5 Test methods	7
5.1 Principle	7
5.2 Materials and reagents.....	8
5.2.1 Test organisms.....	8
5.2.2 Culture media and reagents	8
5.2.3 Test surface	11
5.3 Apparatus and glassware	12
5.3.1 General.....	12
5.3.2 Usual microbiological laboratory equipment and, in particular, the following:	12
5.4 Preparation of test organism suspensions and product test solutions.....	13
5.4.1 Test organism suspensions	13
5.4.2 Product test solutions.....	19
5.5 Procedure for assessing the bactericidal, yeasticidal and fungicidal activity of the product.....	19
5.5.1 Choice of experimental conditions	19
5.5.2 Test procedure.....	20
5.5.3 Counting of the test mixtures.....	23
5.6 Calculation and expression of results.....	24
5.6.1 Calculation of data	24
5.6.2 Verification of methodology.....	25
5.6.3 Expression of results.....	25
5.6.4 Conclusion.....	26
5.7 Test report.....	26
Annex A (informative) Corresponding referenced strains	28
Annex B (informative) Neutralizers	29
Annex C (informative) Expression of results with the dilution-neutralization method	31
Annex D (informative) Bactericidal activity on surfaces under clean conditions	33
Annex E (informative) Vacuum drying by desiccator - Instruction of use.....	35
Annex F (informative) Precision of the test result.....	37
Bibliography.....	38

European foreword

This document (EN 17387:2021) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2022, and conflicting national standards shall be withdrawn at the latest by February 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document describes a surface test method for establishing whether a chemical disinfectant in the area and fields described in the scope (Clause 1) has or does not have bactericidal and/or fungicidal or yeasticidal activity on non-porous surfaces without mechanical action.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, and microorganisms on surfaces...) reflect parameters which are found in practical situations including conditions which can influence the action of disinfectants.

However, for some applications the recommendations of use of a product can differ and therefore additional test conditions need to be used.

This document is not intended to be used when product is applied via an automatic airborne disinfection method; in such cases, see EN 17272.

1 Scope

This document specifies a test method and the minimum requirements for bactericidal and yeasticidal and additionally fungicidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water – or in the case of ready-to-use products – with water.

NOTE Dilutions are necessary as three concentrations in the active to non-active range are tested.

This document applies to products that are used in the medical area for disinfecting non-porous surfaces without mechanical action.

This document applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:

- in hospitals, in community medical facilities and in dental institutions;
- in clinics of schools, of kindergartens and of nursing homes; and can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patients.

EN 14885 specifies in detail the relationship of the various tests to one another and to use recommendations.

Using this document, it is possible to determine the activity of products like commercial formulations or active substances on bacteria and/or fungi in the conditions in which they are used and therefore it corresponds to a phase 2, step 2 test.

This method excludes the evaluation of the activity of products against mycobacteria and bacterial spores.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12353, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>