SLOVENSKI STANDARD
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Kemična razkužila in antiseptiki - Uporaba evropskih standardov za kemična razkužila in antiseptike

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Chemische Desinfektionsmittel und Antiseptika - Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika

Antiseptiques et désinfectants chimiques - Application des Normes européennes sur les antiseptiques et désinfectants chimiques

Ta slovenski standard je istoveten z: **EN 14885:2022**

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EUROPEAN STANDARD

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English Version

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Antiseptiques et désinfectants chimiques - Application des Normes européennes sur les antiseptiques et désinfectants chimiques

Chemische Desinfektionsmittel und Antiseptika - Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika

This European Standard was approved by CEN on 20 June 2022.

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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.

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

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

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European foreword

This document (EN 14885:2022) 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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

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.

This document supersedes EN 14885:2018 and CEN/TR 17296:2018.

EN 14885:2018 was revised to update the information on existing standards, to include standards published since 2018 and to give more details how to use the standards for making claims. CEN/TC 216 has prepared a series of standards on chemical disinfectants and antiseptics specifying requirements and test methods. The purpose of this document is to specify the relationship of the various standards to one another and to claims and use recommendations.

To allow for different requirements in different areas of application, separate tests and pass criteria have been or will be prepared for each of the following three areas of application: medical, veterinary, and a group comprising food, industrial, domestic and institutional areas.

This document only refers to test methods which are currently included in the work programme of CEN/TC 216 and which are described in Clause 2. It is likely that additional standards which relate to specific situations will be produced at a later time.

This document was revised to adapt it to the latest state of CEN/TC 216, to correct errors and ambiguities. The following is a list of significant changes since the last edition:

— Scope (Clause 1): the different working groups added; safety issues when performing the tests addressed as well as the information that EN 14885 is periodically updated;

— Normative references (2) updated, the standards revised after the last revision of EN 14885 are signposted;

— Terms and definitions (3) *deleted*: “bactericide”, “fungicide” and similar ones; *added:* “active substance”, “contact time”, “limiting test organism”, “test”; *changed*: “antisepsis”, “chemical disinfection”, “virucidal activity”, “microbistatic activity” defined for all other deleted ” -static” definitions, “product”, ”test organism”;

— Clarification of the text in 4.2.4 as well as in 4.2.5 (former “4.2.5” to “4.2.8”);

— New: clarification, that in all standards EN 12353 has to be followed (new 4.2.6);

— Special guidance for certain cases of chemo-thermal disinfection (new 4.2.7);

— Information about concentrations to be tested (new 4.2.8);

— Medical area (4.3), Veterinary area (4.4) and Food, industrial, domestic and institutional areas (4.5) tables and text updated including the clarification for disinfectants used in veterinary care facilities (medical or veterinary);

— Clarification of the text in Clauses 5, 6, 7 and 8;

— The text of Annexes B and C are significantly changed;

— New Annex A “Differentiation of active and non-active substances in a product”;

— New Annex E “Choice of meaningful concentrations when testing products according to the standards”;

— New Annex F “CEN /TC 216 standards in preparation or under revision”;

The changes mentioned above have no impact on the use of test results obtained with reference to the former version of EN 14885 if a standard has not been revised in the meantime. Those results are still valid. If there is a new edition in Clause 2 cited (standard revised) refer to the information in Clause 8.

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 specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development. This document is not intended to represent disinfection policy guidelines, i.e. guidelines for choosing and assessing the suitability of products for particular situations.

The CEN standards relate to only a limited range of microbial species. These have been chosen as representative species taking into account their relative resistance and their relevance to practical use. The handling properties and the microbiological safety have also been considered in choosing the test organisms.

The test methods in this document are based on the current scientific state of the art. It is recognized that at the present time there is only limited knowledge regarding the relationship between the activity of products as determined by suspension as compared with surface tests, and the relevance of the results of both tests to conditions of use.

Chemical disinfectants and antiseptics need to be always be used responsibly. This need to take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.

1 Scope

This document specifies the European Standards to which products have to conform in order to support the claims for microbicidal activity which are referred to in this document.

This document also specifies terms and definitions which are used in European Standards.

It is applicable to products for which activity is claimed against the following microorganisms: vegetative bacteria (including mycobacteria and *Legionella*), bacterial spores, yeasts, fungal spores and viruses (including bacteriophages).

It is intended to:

a) enable manufacturers of products to select the appropriate standards to be used in order to provide data which support their claims for a specific product;

b) enable users of the product to assess the information provided by the manufacturer in relation to the use for which they intend to use the product;

c) assist regulatory authorities in assessing claims made by the manufacturer or by the person responsible for placing the product on the market.

It is applicable to products to be used in the area of human medicine, the veterinary area and in food, industrial, domestic and institutional areas.

In the area of human medicine (Working Group 1, i.e. WG 1), it is applicable to chemical disinfectants and antiseptics to be used in areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care

— in hospitals, in community medical facilities, dental institutions and medical laboratories for analyses and research,

— in clinics of schools, of kindergartens and of nursing homes,

— and may also occur in the workplace and in the home. It may also include services such as in laundries and kitchens supplying products directly for the patient.

In the veterinary area (WG 2) it is applicable to chemical disinfectants and antiseptics to be used in the areas of breeding, husbandry, veterinary care facilities, production, transport and disposal of animals and veterinary laboratories for analyses and research. It is not applicable to chemical disinfectants used in the food chain following death and entry to the processing industry.

In food, industrial, domestic and institutional areas (WG 3) it is applicable to chemical disinfectants and antiseptics to be used in processing, distribution and retailing of food of animal or vegetable origin. It is also applicable to products for all public areas where disinfection is not medically indicated (homes, catering, schools, nurseries, transports, hotels, offices etc.) and products used in packaging, biotechnology, laboratories (except laboratories for veterinary and medical analyses and research), pharmaceutical, cosmetic etc. industries.

This document is also applicable to active substances and products under development for which no area of application has yet been specified.

This document will be periodically updated to reflect the current published versions of each standard developed in CEN/TC 216. Independent of this update newly published standards are to be used, even if they are not yet mentioned in EN 14885.

This document does not refer to methods for testing the toxicological and ecotoxicological properties of products or active substances.

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 1040:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1275:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1276:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 1499:2013, *Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)*

EN 1500:2013, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)*

EN 1650:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 1656:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 1657:2016, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 12353:2021, *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 12791:2016+A1:2017, *Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)*

EN 13610:2002, *Chemical disinfectants - Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1)*

EN 13623:2020, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)*

EN 13624:2013, *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)*

EN 13697:2015+A1:2019, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)*

EN 13704:2018, *Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

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)*

EN 14204:2012, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 14347:2005, *Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)*

EN 14348:2005, *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)*

EN 14349:2012, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 14476:2013+A2:2019, *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)*

EN 14561:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14562:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14563:2008, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)*

EN 14675:2015, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1)*

EN 16437:2014+A1:2019, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16438:2014, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16615:2015, *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2)*

EN 16616:2015, *Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)*

EN 16777:2018, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)*

EN 17111:2018, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 17122:2019, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements - Phase2, step2*

EN 17126:2018, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)*

EN 17272:2020, *Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities*

EN 17387:2021, *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)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

NOTE Some recommendations on the use of terminology in the areas of chemical disinfection and antisepsis are given in Annex B.

3.1 Chemical disinfectant or antiseptic procedures and product types

3.1.1
antiseptic
product – excluding antibiotics – that is used to bring about antisepsis

3.1.2
antisepsis
application of an antiseptic on living tissues causing an action on the structure or metabolism of microorganisms to a level judged to be appropriate to prevent and/or limit and/or treat an infection of those tissues

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.11)

3.1.3
chemical disinfectant
product that is capable of chemical disinfection

3.1.4
chemical disinfection
reduction of the number of microorganisms in or on an inanimate or animate matrix, achieved by the irreversible action of a product on their structure or metabolism, to a level judged to be appropriate for a defined purpose

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.11)

Note 2 to entry: Products for antisepsis are excluded

3.1.5
hygienic handrub
treatment of hands by rubbing a product without the addition of water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.6
hygienic handwash
treatment of hands by washing with product and water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.7
instrument disinfection
chemical disinfection of certain instrument surfaces in the medical and veterinary areas by immersion

3.1.8
surface disinfection
chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action

Note 1 to entry: The application includes e.g. wiping, mopping, circulation, flooding, spraying, fogging, etc.

3.1.9
surgical handrub
preoperative treatment of hands by rubbing a product without the addition of water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.10
surgical handwash
preoperative treatment of hands by washing with product and water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.11
textile disinfection
chemical disinfection of textiles through the application of a product by either immersion in a solution or by processing in a washing machine

3.2 Chemical disinfectant or antiseptic action

3.2.1
algaecidal activity
capability of a product to reduce the quantity of algae as test organisms, specified in the corresponding standard(s), under defined conditions

3.2.2
bactericidal activity
capability of a product to reduce the number of viable bacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.3
fungicidal activity
capability of a product to reduce the number of viable yeast cells and mould spores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.4
microbicidal activity
microbiocidal activity
capability of a product to reduce the number of relevant test organisms including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts, specified in the corresponding standard(s)

Note 1 to entry: The above term is a general term, not to be used for claims according to Clause 7 c).

3.2.5
microbistatic activity
microbiostatic activity
capability of a product to inhibit the growth of relevant test organisms, including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts under defined conditions

Note 1 to entry: The above term and related terms like “bacteriostatic”, “fungistatic” are used in CEN / TC 216 standards but cannot be used for claims according to the scope (Clause 1).

3.2.6
mycobactericidal activity
capability of a product to reduce the number of viable mycobacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.7
oocysticidal activity
capability of a product to reduce the number of oocysts of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.8
phagocidal activity
capability of a product to reduce the number of infectious bacteriophage particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.9
sporicidal activity levels
different levels of sporicidal activity with various gradations against aerobic and/or anaerobic bacterial endospores

Note 1 to entry: The x different levels are: sporicidal activity (3.2.9.1), Sporicidal activity against *C. difficile* in human medicine (3.2.9.2).

3.2.9.1
sporicidal activity
capability of a product to reduce the number of viable aerobic and anaerobic bacterial endospores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.9.2
sporicidal activity against *C. difficile* in human medicine
capability of a product to reduce the number of viable bacterial endospores of *C. difficile*, specified in the corresponding standard(s), under defined conditions

3.2.10
tuberculocidal activity
capability of a product to reduce the number of viable cells of relevant Mycobacteria as test organism, specified in the corresponding standard(s), under defined conditions

3.2.11
virucidal activity levels
different levels of virucidal activity with various gradations

Note 1 to entry: The three different levels are: virucidal activity (3.2.11.1), limited spectrum virucidal activity (3.2.11.2) and virucidal activity against enveloped viruses (3.2.11.3)

3.2.11.1
virucidal activity
capability of a product to reduce the number of infectious virus particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

Note 1 to entry: virucidal activity covers enveloped and non-enveloped viruses

3.2.11.2
limited spectrum virucidal activity
capability of a product to reduce the number of infectious virus particles using certain non-enveloped viruses as test organisms, specified in the corresponding standard(s), under defined conditions, thus covering virucidal activity against these test organisms, and additionally defined other non-enveloped virus(es) and all enveloped viruses