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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 14885:2018 sisaldab Euroopa standardi EN 14885:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 14885:2018 consists of the English text of the European standard EN 14885:2018.
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.
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EUROPEAN STANDARD

EN 14885

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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 12 October 2018.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 14885:2018) 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of an identical text or by endorsement, at the latest by May 2019, and conflicting national standards shall be withdrawn at the latest by May 2019.

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 14885:2015.

EN 14885:2015 was revised to update the information on existing standards, to include standards published since 2015 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 European Standard 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 European Standard 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:

- inclusion of new and revised standards (EN 12791, EN 13727/A2, EN 14476/A1, EN 16615 and EN 16616).

The changes mentioned above have no impact on the use of test results obtained with reference to the former version of EN 14885.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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 should always be used responsibly. This should 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 European Standard.

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, 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 and dental institutions,
- 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 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. 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 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, 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 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 1499, *Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)*

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

EN 1656, *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, *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 12791, *Chemical disinfectants and antiseptics — Surgical hand disinfection — Test method and requirements (phase 2, step 2)*

EN 13623, *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, *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, *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, *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, *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, *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 14348, *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, *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, *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, *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, *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, *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, *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, *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, *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, *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, *Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - 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 <http://www.iso.org/obp>

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

3.1 Chemical disinfectant or antiseptic procedures and product types

3.1.1

antiseptic

product – excluding antibiotics – that is used to bring about antiseptis