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BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN 14885:2022, incorporating corrigendum March 2023. It supersedes BS EN 14885:2018 and PD CEN/TR 17296:2018, which are withdrawn.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by CEN corrigendum March 2023 is indicated in the text by AC1 AC1.

The UK participation in its preparation was entrusted to Technical Committee CH/216, Chemical disinfectants and antiseptics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2023

ISBN 978 0 539 26341 1

ICS 11.080.20; 71.100.35

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2023.

Amendments/corrigenda issued since publication

Date	Text affected
30 April 2023	Implementation of CEN corrigendum March 2023

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EUROPÄISCHE NORM

July 2022

ICS 11.080.20; 71.100.35

Supersedes EN 14885:2018, CEN/TR 17296:2018

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.

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.



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COMITÉ EUROPÉEN DE NORMALISATION
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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*: "antiseptics", "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);

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- 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.

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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.

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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.