SLOVENSKI STANDARD
SIST EN 14885:2015

01-oktober-2015

Nadomešča:
SIST EN 14885:2007

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 14885:2015**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics
71.100.35	Kemikalije za dezinfekcijo v industriji in doma	Chemicals for industrial and domestic disinfection purposes

SIST EN 14885:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14885

August 2015

ICS 71.100.35

Supersedes EN 14885:2006

English Version

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

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European foreword

This document (EN 14885:2015) 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of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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

This document supersedes EN 14885:2006.

EN 14885:2006 was revised to update the information on existing standards, to include standards published since 2006 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, e.g. chemical disinfection of textiles, will be produced at a later time.

This document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording and to improve its readability and thereby make it more understandable. The following is a list of significant changes since the last edition:

— some definitions were added, some were changed;

— the relevance of phase 1 tests was clarified;

— the relationship between claims for a given product and test results is described in greater detail;

— the use of standards outside their defined scope is now defined;

— the fields of application in the different areas are described in much greater detail;

— recommendations how to deal with the imprecision of the test methods are given;

— recommendations how to use the standards for proficiency testing (quality control) are given;

— the impact of changes of standards are defined;

— the main aims, scope, safety aspects, design, performance and evaluation of results of phase 3 tests (field tests) are described.

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 organizations 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

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

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1276, *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, *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 1650, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas — Test method and requirements (phase 2, step 1)*

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 requirement (phase 2/step 2)*

EN 13610, *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, *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)*

3 Terms and definitions

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

NOTE Some recommendations on the use of terminology in the areas of chemical disinfection and antisepsis 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 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

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 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

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. circulation, flooding, spraying, fogging, wiping 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
bactericide
product that irreversibly inactivates vegetative bacteria under defined conditions

Note 1 to entry: The adjective derived from “bactericide” is “bactericidal”.

3.2.2
bactericidal activity
capability of a product or active substance to produce a reduction in the number of viable bacterial cells of relevant test organisms under defined conditions

3.2.3
bacteriostatic activity
capability of a product to inhibit the growth of viable bacterial cells of relevant test organisms under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7 c).

3.2.4
fungicide
product that irreversibly inactivates fungi (moulds and yeasts) and their spores under defined conditions

Note 1 to entry: The adjective derived from “fungicide” is “fungicidal”.

3.2.5
fungicidal activity
capability of a product or active substance to produce a reduction in the number of viable yeast cells and mould spores of relevant test organisms under defined conditions

3.2.6
fungistatic activity
capability of a product to inhibit the germination of mould spores and/or the growth of viable yeast cells of relevant test organisms under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7 c).

3.2.7
microbicide
product that irreversibly inactivates vegetative bacteria and/or bacterial endospores and/or fungi (moulds and/or yeasts, including fungal spores) and/or viruses under defined conditions

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

3.2.8
microbicidal activity
capability of a product or active substance to produce under defined test conditions a reduction in the number of relevant test organisms including viable bacterial cells and/or viable vegetative yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles

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

3.2.9
mycobactericide
product that irreversibly inactivates mycobacteria under defined conditions

Note 1 to entry: The adjective derived from “mycobactericide” is “mycobactericidal”.

3.2.10
mycobactericidal activity
capability of a product or active substance to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions

3.2.11
phagocidal activity
capability of a product or active substance to produce a reduction in the number of infectious bacteriophage particles of relevant test organisms under defined conditions

3.2.12
sporicide
product that irreversibly inactivates bacterial endospores under defined conditions

Note 1 to entry: The adjective derived from “sporicide” is “sporicidal”.

3.2.13
sporicidal activity
capability of a product or active substance to produce a reduction in the number of viable bacterial endospores of relevant test organisms under defined conditions

3.2.14
sporistatic activity
capability of a product to inhibit the germination of bacterial endospores under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7.

3.2.15
tuberculocide
product that irreversibly inactivates *Mycobacterium tuberculosis* under defined conditions

Note 1 to entry: The adjective derived from “tuberculocide” is “tuberculocidal”.

Note 2 to entry: The test organism used for demonstrating the activity is *Mycobacterium terrae*.

3.2.16
tuberculocidal activity
capability of a product or active substance to produce a reduction in the number of viable cells of the test organism *Mycobacterium terrae* under defined conditions

3.2.17
virucide
product that irreversibly inactivates viruses under defined conditions

Note 1 to entry: The adjective derived from “virucide” is “virucidal”.

Note 2 to entry: The term virucide includes the inactivation of vertebrate viruses and/ or bacteriophages.

3.2.18
virucidal activity
capability of a product or active substance to produce a reduction in the number of infectious virus particles of relevant test organisms under defined conditions

Note 1 to entry: Limited spectrum virucidal activity is a claim for hygienic handrub and hygienic handwash products using *Adenovirus* and *Murine Norovirus* as test organisms, thus including activity against the test viruses and all enveloped viruses.

3.2.19
yeasticide
product that irreversibly inactivates yeasts under defined conditions

Note 1 to entry: The adjective derived from “yeasticide” is “yeasticidal”.

3.2.20
yeasticidal activity
capability of a product or active substance to produce a reduction in the number of viable yeast cells of relevant test organisms under defined conditions

3.3 General terms

3.3.1
additional test conditions
test conditions that are optional and not obligatory, that may be used for additional product claims and that may be found in the same standard or in an additional standard

3.3.2
Interfering substance
see “soiling”

3.3.3
neutralizer
chemical agent or formulation that suppresses the residual microbicidal activity of a product or active substance within a specific test but does not inactivate or inhibit the test organism

3.3.4
product
formulation used as a chemical disinfectant or antiseptic

Note 1 to entry: A ready-to-use product is a product used undiluted.

3.3.5
soiling
the term “soiling” is represented in the standards by the term “interfering substance”

3.3.5.1
clean conditions
conditions representative of surfaces which have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “low level soiling”. The term “low level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.5.2
dirty conditions
conditions representative of surfaces which are known to or may contain organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “high level soiling”. The term “high level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.6
test organism
strain of a microorganism selected for testing products or active substances within a standardized test

Note 1 to entry: For the purpose of this European Standard, the term microorganism includes vegetative bacteria, bacterial spores, yeasts, mould spores and viruses.

4 Procedures for claiming activity

4.1 Category of tests

The tests are categorised on a modular basis as follows:

— **Phase 1 tests** are quantitative suspension tests to establish that active substances or products under development have bactericidal, fungicidal or sporicidal activity without regard to specific areas of application. Phase 1 tests cannot be used for any product claim.

— **Phase 2** comprises two steps:

a) **Phase 2, step 1 tests** are quantitative suspension tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity under simulated practical conditions appropriate to its intended use;

b) **Phase 2, step 2 tests** are quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity when applied to a surface or skin under simulated practical conditions (e.g. surface, instrument, handwash and handrub tests);

— **Phase 3 tests** are field tests under practical conditions. Applicable methodologies for this type of test are not yet available, but may be developed in the future. Guidance on the design of phase 3 tests and the use of data from phase 3 tests is provided in Annex C.

NOTE In the following phase 2, step 1 is mostly shortened to “2,1” or “2/1” and phase 2, step 2 to “2,2” or “2/2”.

The phase 2, step 1 tests prove the irreversible inactivation of microorganisms. This test design provides relevant information about the activity of the product against microorganisms in suspension. Desiccated microorganisms may be stressed and may offer different challenges.

Phase 2, step 2 tests provide information about the activity against desiccated microorganisms on inanimate surfaces or on living tissues or against non-desiccated microorganisms on living tissues.

Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time and interfering substances) shall be carried out as specified in the standard.

Phase 2, step 1 and phase 2, step 2 tests are generally needed in combination to support efficacy claims for disinfectants or antiseptics. Only in exceptional cases deviation from this principle is allowed (see relevant applications below and Annex B). Both results shall be taken into account in determination of the label claim.

4.2 General

4.2.1 In order to determine that an active substance or a product under development has microbicidal properties, it shall be tested in accordance with and shall conform to the relevant test conditions and requirements of the European phase 1 standards.

4.2.2 For the medical area see 4.3, for the veterinary area see 4.4, for the food, industrial, domestic and institutional areas see 4.5. The standards specified in 4.3, 4.4 or 4.5 may be used to support product claims of activity/conformity to this European Standard on the basis of criteria specified in those standards (minimum requirements, obligatory and/or specified additional conditions).

4.2.3 When recommendations for use are made based on the standards referenced in EN 14885 these shall be supported by test results relevant for this recommendation, e.g. a result for 30 min contact time does not allow a claim for 10 min (but a result for 10 min allows a claim for 30 min if the same product concentration is recommended for use). It is not possible to extend or shorten the time for use beyond the limits (i.e. the minimum and maximum *additional* contact times in the medical, veterinary, food, industrial, domestic and institutional areas) specified in standards referred to in EN 14885.

4.2.4 The product marketed shall be equivalent to the one tested. Equivalent means that it contains the same active substances in the same quantity and that only substances of no proven impact on the product’s activity such as fragrance or colouring are non-identical.

4.2.5 Where there is no appropriate standard for an application within a specific area, a standard from another area may be recommended for use. If later on an appropriate standard is published, this new standard shall be used.