



SLOVENSKI STANDARD

SIST EN 14885:2007

01-april-2007

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 relatives aux antiseptiques et désinfectants chimiques

Ta slovenski standard je istoveten z: EN 14885:2006

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 14885:2007

en;fr;de

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ICS 11.080.20; 71.100.35

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 6 August 2006.

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 Central Secretariat or to any CEN member.

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Foreword

This document (EN 14885:2006) 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of an identical text or by endorsement, at the latest by May 2007, and conflicting national standards shall be withdrawn at the latest by May 2007.

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.

The 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 laundry, will be produced at a later time.

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

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Introduction

This European Standard specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants, antiseptics including active substances, in order to support claims that they have specific properties appropriate to their intended application. It 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 called up in this European Standard are based on current scientific knowledge. It is recognised 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.

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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 standard.

This European Standard also specifies the terms and definitions which are used in two or more of the European Standards.

It is applicable to products for which activity is claimed against the following micro-organisms: vegetative bacteria, bacterial spores, fungi, fungal spores and viruses.

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 competent bodies in assessing claims made by the manufacturer or 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 are medically indicated. Such indications occur in patient care:

- in hospitals, in community medical facilities and dental institutions,
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- 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 products for which no particular area of application is specified (e.g. active substances under development).

The European Standard does not refer to methods for testing the toxicological and ecotoxicological properties of products.

2 Normative references

The following referenced documents are indispensable for the application 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, *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, *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, *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 veterinary field — 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)*

prEN 12054¹⁾, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine — 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 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 13624, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used 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)*

1) Under development.

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 of chemical disinfectants for instruments used 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 14347, *Chemical disinfectants and antiseptics — Basic sporicidal activity — Test method and requirements (phase 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 field on non-porous surfaces without mechanical action — Test method and requirements (phase 2, step 2)*

EN 14476, *Chemical disinfectants and antiseptics — Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine — Test method and requirements (phase 2, step 1)*

EN 14561, *Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants 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)*

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 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 antiseptics

3.1.2

antisepsis

application of an antiseptic on living tissues causing an action on the structure or metabolism of micro-organisms 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 micro-organisms 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

product used for post-contamination treatment that involves rubbing hands, without the addition of water, which is directed against transiently contaminating micro-organisms to prevent their transmission regardless of the resident skin flora

3.1.6

hygienic handwash

product used for post-contamination treatment that involves washing hands, which is directed against transiently contaminating micro-organisms to prevent their transmission regardless of the resident skin flora

3.1.7

instrument disinfection (surface disinfection by immersion)

chemical disinfection of certain instruments in the medical and veterinary areas by immersion

3.1.8

surface disinfection

chemical disinfection of a solid surface, excluding those of certain medical and veterinary instruments (3.1.7) by the application of a product

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NOTE The application includes e.g. circulation, dipping, flooding, immersion, spraying, wiping.

3.1.9

surgical handrub

product used for preoperative treatment that involves rubbing hands, without the addition of water, which is directed against the flora of micro-organisms on hands to prevent the transmission of micro-organisms into the surgical wound

3.1.10

surgical handwash

product used for preoperative treatment that involves washing hands, which is directed against the flora of micro-organisms on hands to prevent the transmission of micro-organisms into the surgical wound

3.2 Chemical disinfectant or antiseptic action

3.2.1

bactericide

product that kills vegetative bacteria under defined conditions

NOTE The adjective derived from "bactericide" is "bactericidal".

3.2.2

bactericidal activity

capability of a product 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 bacteria under defined conditions

3.2.4**fungicide**

product that kills fungi (moulds and yeasts) and their spores under defined conditions

NOTE The adjective derived from “fungicide” is “fungicidal”.

3.2.5**fungicidal activity**

capability of a product to produce a reduction in the number of viable vegetative yeast cells and mould spores of relevant test organisms under defined conditions

3.2.6**fungistatic activity**

capability of a product to inhibit the growth of fungi (moulds and/or yeasts) under defined conditions

3.2.7**mycobactericide**

product that kills mycobacteria under defined conditions

NOTE The adjective derived from “mycobactericide” is “mycobactericidal”.

3.2.8**mycobactericidal activity**

capability of a product to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions

3.2.9**sporicide**

product that kills dormant bacterial spores under defined conditions

NOTE The adjective derived from “sporicide” is “sporicidal”.

3.2.10**sporicidal activity**

capability of a product to produce a reduction in the number of viable bacterial spores of relevant test organisms under defined conditions

3.2.11**sporistatic activity**

capability of a product to inhibit the germination of dormant bacterial spores under defined conditions

3.2.12**tuberculocide**

product that kills *Mycobacterium tuberculosis* under defined conditions

NOTE The adjective derived from “tuberculocide” is “tuberculocidal”.

3.2.13**tuberculocidal activity**

capability of a product to kill *Mycobacterium tuberculosis*, demonstrated by the capability to produce a reduction in the number of viable cells of the test organism *Mycobacterium terrae* under defined conditions

3.2.14**virucide**

product that inactivates viruses under defined conditions

NOTE The adjective derived from “virucide” is “virucidal”.

3.2.15

virucidal activity

capability of a product to produce a reduction in the number of infectious virus particles of relevant test organisms under defined conditions

3.2.16

yeasticide

product that kills yeasts under defined conditions

NOTE The adjective derived from “yeasticide” is “yeasticidal”.

3.2.17

yeasticidal activity

capability of a product 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

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

3.3.2

dirty conditions

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

3.3.3

high-level soiling

condition representative of surfaces with regard to the veterinary area, where heavy soiling can be expected

NOTE This term has been introduced to avoid confusion in the veterinary area where two levels of soiling are relevant.

3.3.4

low-level soiling

condition representative of surfaces, with regard to the veterinary area, where a level of soiling can be expected, that is equivalent to dirty conditions (3.3.2)

NOTE This term has been introduced to avoid confusion in the veterinary area where two levels of soiling are relevant.

3.3.5

neutralizer

chemical agent or formulation that suppresses the residual microbicidal activity of a product within a specific test but does not kill, inactivate or inhibit the test organisms

3.3.6

product

chemical agent or formulation used as a chemical disinfectant or antiseptic

3.3.7

test organism

strain of a micro-organism selected for testing products within a standardised test

NOTE For the purpose of this European Standard the term micro-organism includes vegetative bacteria, bacterial spores, fungi, fungal spores and viruses.