SLOVENSKI STANDARD
SIST EN 17387:2022

01-januar-2022

Kemična razkužila in antiseptiki - Kvantitativni preskus na neporoznih površinah brez mehanskega delovanja za vrednotenje baktericidnega in/ali fungicidnega delovanja in delovanja kemičnih razkužil na kvasovke v humani medicini - Preskusna metoda in zahteve (faza 2, stopnja 2)

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)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Versuch zur Bestimmung der bakteriziden und levuroziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich auf nicht porösen Oberflächen ohne mechanische Einwirkung - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif pour l'évaluation de l'activité bactéricide et levuricide et/ou fongicide des désinfectants chimiques utilisés en médecine sur des surfaces non poreuses sans action mécanique - Méthode d'essai et exigences (phase 2, étape 2)

Ta slovenski standard je istoveten z: **EN 17387:2021**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

SIST EN 17387:2022 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 17387

August 2021

ICS 11.080.20; 71.100.35

English Version

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)

Antiseptiques et désinfectants chimiques - Essai quantitatif pour l'évaluation de l'activité bactéricide et levuricide et/ou fongicide des désinfectants chimiques utilisés en médecine sur des surfaces non poreuses sans action mécanique - Méthode d'essai et exigences (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Versuch zur Bestimmung der bakteriziden und levuroziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich auf nicht porösen Oberflächen ohne mechanische Einwirkung - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 25 January 2021.

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.

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

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

Ref. No. EN 17387:2021 E

Contents

Page

European foreword

This document (EN 17387:2021) 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 2022, and conflicting national standards shall be withdrawn at the latest by February 2022.

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.

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 describes a surface test method for establishing whether a chemical disinfectant in the area and fields described in the scope (Clause 1) has or does not have bactericidal and/or fungicidal or yeasticidal activity on non-porous surfaces without mechanical action.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, and microorganisms on surfaces...) reflect parameters which are found in practical situations including conditions which can influence the action of disinfectants.

However, for some applications the recommendations of use of a product can differ and therefore additional test conditions need to be used.

This document is not intended to be used when product is applied via an automatic airborne disinfection method; in such cases, see EN 17272.

1 Scope

This document specifies a test method and the minimum requirements for bactericidal and yeasticidal and additionally fungicidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water – or in the case of ready-to-use products – with water.

NOTE Dilutions are necessary as three concentrations in the active to non-active range are tested.

This document applies to products that are used in the medical area for disinfecting non-porous surfaces without mechanical action.

This document applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities and in dental institutions;

— in clinics of schools, of kindergartens and of nursing homes; and can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patients.

EN 14885 specifies in detail the relationship of the various tests to one another and to use recommendations.

Using this document, it is possible to determine the activity of products like commercial formulations or active substances on bacteria and/or fungi in the conditions in which they are used and therefore it corresponds to a phase 2, step 2 test.

This method excludes the evaluation of the activity of products against mycobacteria and bacterial spores.

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 12353, *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 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.2 Symbols and abbreviations

c	is the sum of V_C-values taken into account
cfu	colony forming units
d	is the dilution taken into account, lower dilution factor
m, m'	are the two replicas at the lower dilution expressed as cfu;
n, n'	are the two replicas at the higher dilution expressed as cfu;
n	is the number of V_C-values taken into account
N	number of cells per ml in the test suspension
N_c	lg number of cfu recovered from the test surface in the water control
N_C	counting of the cfu in the neutralizer control
N_d	lg number of cfu recovered from the test surface in the test
N_T	counting of the cfu in the method validation
N_{ts}	number of colony forming units remaining on the test surface
R	reduction
V	is the volume of the inoculated into the plate expressed in ml

4 Requirements

The product shall demonstrate at least a 5 decimal log (lg) reduction for bacteria and at least a 4 decimal log (lg) reduction for fungi, when tested in accordance with Table 1 and 5.5.

NOTE The 5 lg reduction is deemed necessary for the medical area to minimize the risk for the patients.

Table 1 — Experimental conditions

Test conditions	Bactericidal activity	Yeasticidal activity	Fungicidal activity
Minimum spectrum of test organisms	*Staphylococcus aureus* *Enterococcus hirae* *Pseudomonas aeruginosa*	*Candida albicans*	*Aspergillus brasiliensis* *Candida albicans*
additional	any relevant test organism		
Test temperature	according to the manufacturer's recommendation, but between (4 ± 1) °C to (30 ± 1) °C For tests performed at room temperature, the range shall be (21,5 ± 3,5) °C		
Contact time	according to the manufacturer's recommendation, but at minimum 1 min and no longer than 5 min or 60 min[a] (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)		
Interfering substance			
clean conditions	0,3 g/l bovine albumin		
dirty conditions	3,0 g/l bovine albumin plus 3,0 ml/l erythrocytes		
additional	any relevant substance		

[a] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, shall be tested with a contact time of maximum 5 min. The same applies where the contact time of the product shall be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

NOTE For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.

5 Test methods

5.1 Principle

A test suspension of bacteria or fungi in a solution of interfering substances (5.2.2.8) is inoculated onto a test stainless steel surface and dried. A sample of the product under test is applied in a manner that completely covers the dried test organisms. The surface is maintained at the temperature and contact time exemplified in Clause 4 and 5.5.1. At the end of the contact time the surface is transferred to a previously validated neutralization medium to suppress any product activity. The number of surviving test organisms which can be recovered from the surface is determined quantitatively.

The number of bacteria or fungi on a test surface treated with hard water (or water in case of ready to use products) in place of the product under test is also determined and the reduction in viable counts attributed to the product is calculated as the difference between the two test surfaces' results.

5.2 Materials and reagents

5.2.1 Test organisms

The bactericidal activity shall be evaluated using the following strains[1]:

— *Staphylococcus aureus* ATCC 6 538;

— *Enterococcus hirae* ATCC 10 541;

— *Pseudomonas aeruginosa* ATCC 15 442.

The yeasticidal activity shall be evaluated using the following strain[1]:

— *Candida albicans* ATCC 10 231.

The fungicidal activity shall be evaluated using the following strains[1]:

— *Aspergillus brasiliensis* ATCC 16 404;

— *Candida albicans* ATCC 10 231.

If required for specific applications, additional strains may be chosen.

NOTE See Annex A for corresponding strain numbers in some other culture collections.

If additional test organisms are used, they shall be incubated under optimum growth conditions (temperature, time, atmosphere, media) noted in the test report. If the additional test organisms selected do not correspond to the specified strains, their suitability for supplying the required inocula shall be verified. If these additional test organisms are not classified at a reference centre, their identification characteristics shall be stated. In addition, they shall be held by the testing laboratory or national culture collection under a reference for five years.

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this document refer to the anhydrous salts. Hydrated forms may be used as an alternative, but the weights required shall be adjusted to allow for consequent molecular weight differences.

The reagents shall be of analytical grade and/or appropriate for microbiological purposes. They shall be free from substances that are toxic or inhibitory to the test organisms.

To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed.

For each culture medium and reagent, a time limitation for use should be fixed.

All specified pH values are measured at (20 ± 1) °C.

[1] The ATCC numbers are the collection numbers of strains supplied by these culture collections. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of the product named.

5.2.2.2 Water

The water shall be freshly glass-distilled water and not demineralized water. If distilled water of adequate quality is not available, water for injections can be used.

Sterilize in the autoclave [5.3.2.1a)]. Sterilization is not necessary if the water is used e.g. for preparation of culture media and subsequently sterilized.

NOTE See 5.2.2.7 for the procedure to prepare hard water.

5.2.2.3 Tryptone soya agar (TSA)

For maintenance of bacterial strains and performance of viable counts.

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
Sodium chloride (NaCl)	5,0 g
Agar	15,0 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization the pH (5.3.2.6) of the medium shall be equivalent to 7,2 ± 0,2.

5.2.2.4 Malt extract agar (MEA)

For maintenance of fungal strains, sporulation and performance of viable counts.

Malt extract [food grade (e.g. Christomalt powder from Difal) or an equivalent extract that is not highly purified and not only based on maltose (e.g. Malt extract from OXOID)][2]	30,0 g
Agar	15,0 g
Water (5.2.2.2)	to 1 000,0 ml

However, if there are problems producing at least 75 % spiny spores see 5.4.1.3.

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization, the pH (5.3.2.6) of the medium shall be equivalent to 5,6 ± 0,2.

In case of an encountering problems with neutralization (5.5.2.3 and 5.5.2.4), it may be necessary to add neutralizer (5.2.2.6) to MEA (5.2.2.4). Annex B gives guidance on the neutralizers that can be used. It is recommended not to use neutralizer that causes opalescence in the agar.

5.2.2.5 Diluent

Tryptone sodium chloride solution:

Tryptone, pancreatic digest of casein	1,0 g
Sodium chloride	8,5 g
Water (5.2.2.2)	to 1 000,0 ml

[2] This Malt extracts from Difal and OXOID are examples of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of this product.

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization, the pH (5.3.2.6) of the diluent shall be equivalent to 7,0 ± 0,2.

5.2.2.6 Neutralizer

The neutralizer shall be validated for the product being tested in accordance with 5.5.2.3 and 5.5.2.4. It shall be sterile.

NOTE Information on neutralizers that have been found to be suitable for some categories of products is given in Annex B.

5.2.2.7 Hard water for dilution of products

For the preparation of 1 l of hard water, the procedure is as follows:

— Prepare solution A: dissolve 19,84 g magnesium chloride ($MgCl_2$) and 46,24 g calcium chloride ($CaCl_2$) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.19) or in the autoclave [5.3.2.1 a)]. Autoclaving – if used - can cause a loss of liquid. In this case make up to 1 000 ml with water (5.2.2.2) under aseptic conditions. Store the solution in the refrigerator (5.3.2.15) for no longer than one month.

— Prepare solution B: dissolve 35,02 g sodium bicarbonate ($NaHCO_3$) in water (5.2.2.2) and dilute to 1000 ml. Sterilize by membrane filtration (5.3.2.19). Store the solution in the refrigerator (5.3.2.15) for no longer than one week.

— Place 600 ml to 700 ml of water (5.2.2.2) in a 1 000 ml volumetric flask (5.3.2.13) and add 6,0 ml of solution A, then 8,0 ml of solution B. Mix and dilute to 1 000 ml with water (5.2.2.2). The pH (5.3.2.6) of the hard water shall be 7,0 ± 0,2. If necessary, adjust the pH by using a solution of approximately 40 g/l (about 1 mol/l) of sodium hydroxide (NaOH) or approximately 36,5 g/l (about 1 mol/l) of hydrochloric acid (HCl).

The hard water shall be freshly prepared under aseptic conditions and used within 12 h.

NOTE When preparing the product test solutions (5.4.2), the addition of the product to the hard water produces different final water hardness in each test tube. In any case, the final hardness expressed as calcium carbonate ($CaCO_3$) is lower than 375 mg/l in the test tube.

5.2.2.8 Interfering substance

5.2.2.8.1 General

The interfering substance shall be chosen according to the conditions of use laid down for the product.

The interfering substance shall be sterile and prepared at 2 times its final concentration in the test.

For any additional interfering substance, the ionic composition (e.g. pH, calcium and/or magnesium hardness) and chemical composition (e.g. mineral substances, protein, carbohydrates, lipids, detergents) shall be fully defined.

NOTE The term “interfering substance” is used even if it contains more than one substance.

The methods of preparation and sterilization together with the composition shall be noted in the test report (5.7).

5.2.2.8.2 Bovine albumin solution

Bovine albumin solutions for the test conditions shall be prepared as follows.

a) Preparation for clean conditions:

— Dissolve 0,3 g of bovine albumin fraction V (suitable for microbiological purposes) in 100 ml of diluent (5.2.2.5).

— Sterilize by membrane filtration (5.3.2.19).

— Dilute to the 1/5th with diluent (5.2.2.5).

— Keep in the refrigerator and use within one month.

The final concentration of bovine albumin in the test procedure (5.5.2) is 0,3 g/l.

b) Preparation for dirty conditions:

— Dissolve 3,0 g of bovine albumin fraction V (suitable for microbiological purposes) in 97 ml of diluent (5.2.2.5).

— Sterilize by membrane filtration (5.3.2.19).

— Prepare at least 8,0 ml fresh sterile defibrinated sheep blood. Centrifuge the sheep blood at 800 g_N (5.3.2.14) for 10 min. After discarding the supernatant, resuspend erythrocytes in diluent (5.2.2.5).

— Repeat this procedure at least 3 times, until the supernatant is colourless.

— Resuspend 3 ml of the packed sheep erythrocytes in the 97 ml of sterilized bovine albumin solution (above).

— Dilute to the 1/5th with diluent (5.2.2.5).

— To avoid contamination this mixture should be split in portions probably needed per day and kept in separate containers for a maximum of 7 days in a refrigerator (5.3.2.15).

The final concentration of bovine albumin and sheep erythrocytes in the test procedure (5.5) shall be 3 g/l and 3 ml/l respectively.

5.2.3 Test surface

The test surface is a flat stainless steel 304 ([1],[2]) disc (2 cm diameter) with grade 2b finish on both sides. Only one side of a disc shall be used. The discs shall be used only once and manipulated with forceps (5.3.2.16).

For cleaning, the discs shall be placed in a beaker (minimum size: 50 ml) containing not less than 20 ml of 5 % (V/V) Decon®[3] for 60 min. Immediately rinse the discs twice with water (5.2.2.2) for 10 s to completely remove the cleanser. Do not let the discs dry.

[3] Decon® is an example of a suitable product available commercially. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of this product.