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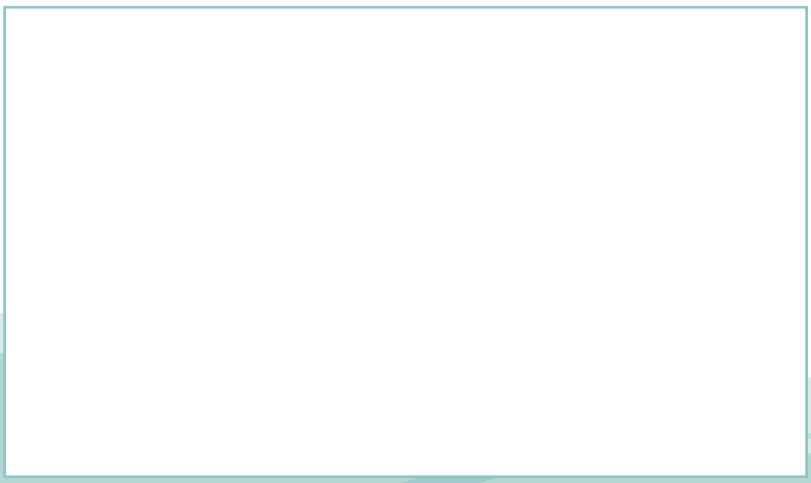
SWEDISH STANDARDS INSTITUTE

Kemiska desinfektionsmedel och antiseptiska medel – Kvantitativt suspensionsprov för utvärdering av den baktericida verkan hos kemiska desinfektionsmedel och antiseptiska medel för användning i livsmedels-, industri-, hem- och institutionsmiljöer – Provningsmetod och krav (fas 2, steg 1)

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)



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Europastandarden EN 1276:2019 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 1276:2019.

Denna standard ersätter SS-EN 1276:2009, utgåva 2.

The European Standard EN 1276:2019 has the status of a Swedish Standard. This document contains the official version of EN 1276:2019.

This standard supersedes the SS-EN 1276:2009, edition 2.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1276

August 2019

ICS 71.100.35

Supersedes EN 1276:2009

English Version

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)

Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l'évaluation de l'activité bactéricide des antiseptiques et des désinfectants chimiques utilisés dans le domaine de l'agro-alimentaire, dans l'industrie, dans les domaines domestiques et en collectivité - Méthode d'essai et prescriptions (phase 2, étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der bakteriziden Wirkung chemischer Desinfektionsmittel und Antiseptika in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 17 June 2019.

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

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European foreword

This document (EN 1276:2019) 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 2020 and conflicting national standards shall be withdrawn at the latest by February 2020.

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 1276:2009.

Data obtained by using the latest version of EN 1276 are still valid.

The main changes in relation to EN 1276:2009 are:

— handrub and handwash test conditions and test requirements have been harmonized with EN 13727;

— interfering substance for breweries, soft drinks, cosmetics and cleaning in place have been deleted. A sentence to allow additional interfering substance for specific applications has been added;

— the obligatory conditions (temperature and contact time) have been deleted. The text has been harmonized with EN 13727 keeping specified time intervals and temperature steps;

— test conditions for temperatures ≥ 40 °C have been added.

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, 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 suspension test for establishing whether a chemical disinfectant or antiseptic has or does not have bactericidal activity in the fields described in the scope.

This laboratory test takes into account practical conditions of application of the product, including contact time, temperature, test organisms and interfering substance, i.e. conditions which may influence its action in practical situations.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to defined test conditions. However, for some applications, the recommendations of use of a product can differ and therefore additional test conditions need to be used.

1 Scope

This document specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water or - in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less, as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products that are used in food, industrial, domestic and institutional areas excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas. The following areas are at least included:

a) processing, distribution and retailing of:

   1) food of animal origin:

      — milk and milk products;

      — meat and meat products;

      — fish, seafood, and related products;

      — eggs and egg products;

      — animal feeds;

      — etc.

   2) food of vegetable origin:

      — beverages;

      — fruits, vegetables and derivatives (including sugar, distillery, etc.);

      — flour, milling and baking;

      — animal feeds;

      — etc.

b) institutional and domestic areas:

   — catering establishments;

   — public areas;

   — public transports;

   — schools;

   — nurseries;

   — shops;

   — sports rooms;

   — waste containers (bins, etc.);

- hotels;
- dwellings;
- clinically non sensitive areas of hospitals;
- offices;
- etc.

c) other industrial areas:

- packaging material;
- biotechnology (yeast, proteins, enzymes, etc.);
- pharmaceutical;
- cosmetics and toiletries;
- textiles;
- space industry, computer industry;
- etc.

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

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 14885:2018, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885:2018 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 https://www.iso.org/obp

4 Requirements

The product shall demonstrate at least a 5 decimal logarithm (lg) reduction (3 lg for handwashes) when diluted with hard water (5.2.2.7) or - in the case of ready-to-use products - with water (5.2.2.2) and tested in accordance with Clause 5 under simulated clean conditions (0,3 g/l bovine albumin solution-5.2.2.8.2) or simulated dirty conditions (3 g/l bovine albumin solution - 5.2.2.8.3) according to its practical applications and under the suitable test conditions as described in 5.5.1.1, Tables 1 and 2 here below.

Table 1 — Test conditions for general purpose disinfection

Test Conditions	**Bactericidal activity**
Test organism (see 5.2.1) **obligatory**	*Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* *E. faecium* (for temperatures ≥ 40 °C)
Example of additional test microorganisms	*Salmonella Typhimurium* *Lactobacillus brevis* *Enterobacter cloacae*
Test temperature	in a range from 4 °C to 60 °C
Contact time	in a range from 1 min to 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)
Clean conditions	0,3 g/l Bovine Albumin for *Staphylococcus aureus*, *Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginosa*
Dirty conditions	3,0 g/l Bovine Albumin for *Staphylococcus aureus*, *Enterococcus hirae, Pseudomonas aeruginosa* and *Escherichia coli*
additional	any relevant substance
Log reduction (decimal lg)	≥ 5 lg
The recommended contact time for the use of the product is within the responsibility of the manufacturer.	