

SVENSK STANDARD

SS-EN 1276:2009

Fastställt/Approved: 2009-11-05
Publicerad/Published: 2009-12-14
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.080.99; 71.100.35

**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)**



Hitta rätt produkt och ett leveranssätt som passar dig

Standarder

Genom att följa gällande standard både effektiviserar och säkrar du ditt arbete. Många standarder ingår dessutom ofta i paket.

Tjänster

Abonnemang är tjänsten där vi uppdaterar dig med aktuella standarder när förändringar sker på dem du valt att abonnera på.

På så sätt är du säker på att du alltid arbetar efter rätt utgåva.

e-nav är vår online-tjänst som ger dig och dina kollegor tillgång till standarder ni valt att abonnera på dygnet runt. Med e-nav kan samma standard användas av flera personer samtidigt.

Leveranssätt

Du väljer hur du vill ha dina standarder levererade. Vi kan erbjuda dig dem på papper och som pdf.

Andra produkter

Vi har böcker som underlättar arbetet att följa en standard. Med våra böcker får du ökad förståelse för hur standarder ska följas och vilka fördelar den ger dig i ditt arbete. Vi tar fram många egna publikationer och fungerar även som återförsäljare. Det gör att du hos oss kan hitta över 500 unika titlar. Vi har även tekniska rapporter, specifikationer och "workshop agreement".

Matriser är en översikt på standarder och handböcker som bör läsas tillsammans. De finns på sis.se och ger dig en bra bild över hur olika produkter hör ihop.

Standardiseringsprojekt

Du kan påverka innehållet i framtida standarder genom att delta i någon av SIS ca 400 Tekniska Kommittéer.

Find the right product and the type of delivery that suits you

Standards

By complying with current standards, you can make your work more efficient and ensure reliability. Also, several of the standards are often supplied in packages.

Services

Subscription is the service that keeps you up to date with current standards when changes occur in the ones you have chosen to subscribe to. This ensures that you are always working with the right edition.

e-nav is our online service that gives you and your colleagues access to the standards you subscribe to 24 hours a day. With e-nav, the same standards can be used by several people at once.

Type of delivery

You choose how you want your standards delivered. We can supply them both on paper and as PDF files.

Other products

We have books that facilitate standards compliance. They make it easier to understand how compliance works and how this benefits you in your operation. We produce many publications of our own, and also act as retailers. This means that we have more than 500 unique titles for you to choose from. We also have technical reports, specifications and workshop agreements.

Matrices, listed at sis.se, provide an overview of which publications belong together.

Standardisation project

You can influence the content of future standards by taking part in one or other of SIS's 400 or so Technical Committees.

Europastandarden EN 1276:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 1276:2009.

Denna standard ersätter SS-EN 1276, utgåva 1.

The European Standard EN 1276:2009 has the status of a Swedish Standard. This document contains the official English version of EN 1276:2009.

This standard supersedes the Swedish Standard SS-EN 1276, edition 1.

! © Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

! © Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.

Standarder kan beställas hos SIS Förlag AB 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), tel +46 8 555 520 00.

Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

SIS Förlag AB, SE 118 80 Stockholm, Sweden. Tel: +46 8 555 523 10. Fax: +46 8 555 523 11.

E-mail: sis.sales@sis.se Internet: www.sis.se

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1276

October 2009

ICS 71.100.35

Supersedes EN 1276:1997

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 20 September 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

	Page
Foreword.....	4
Introduction	5
1 Scope	6
2 Normative references	7
3 Terms and definitions	7
4 Requirements	7
5 Test method.....	8
5.1 Principle.....	8
5.2 Materials and reagents	9
5.2.1 Test organisms	9
5.2.2 Culture media and reagents	9
5.3 Apparatus and glassware	13
5.4 Preparation of test organism suspensions and product test solutions	14
5.4.1 Test organism suspensions (test and validation suspension).....	14
5.4.2 Product test solutions	15
5.5 Procedure for assessing the bactericidal activity of the product	17
5.5.1 General.....	17
5.5.2 Dilution-neutralization method.....	18
5.5.3 Membrane filtration method	20
5.6 Experimental data and calculation.....	22
5.6.1 Explanation of terms and abbreviations	22
5.6.2 Calculation.....	23
5.7 Verification of methodology	26
5.7.1 General.....	26
5.7.2 Control of weighted mean counts.....	26
5.7.3 Basic limits	26
5.8 Expression of results and precision.....	26
5.8.1 Reduction	26
5.8.2 Control of active and non-active product test solution (5.4.2)	27
5.8.3 Limiting test organism and bactericidal concentration.....	27
5.8.4 Precision, replicates	27
5.9 Interpretation of results - conclusion	27
5.9.1 General.....	27
5.9.2 Bactericidal activity for general purposes	27

5.9.3 Bactericidal activity for specific purposes27

5.10 Test report.....28

Annex A (informative) Referenced strains in national collections30

Annex B (informative) Neutralizers and rinsing liquids31

Annex C (informative) Graphical representations of dilution neutralization method and
 membrane filtration method.....33

C.1 Dilution-neutralization method33

C.2 Membrane filtration method35

Annex D (informative) Example of a typical test report37

Test results (bactericidal suspension test)39

Annex E (informative) Precision of the test result.....41

Bibliography.....44

Foreword

This document (EN 1276:2009) 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 April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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 1276:1997.

It was revised to include the results of a collaborative trial (ANDISTAND), to correct obvious errors and ambiguities, to harmonize the structure and wording with other quantitative suspension tests of CEN/TC 216 (existing or in preparation) and to improve the readability of the standard and thereby make it more understandable.

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, 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 the United Kingdom.

Introduction

This European Standard specifies 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 experimental conditions. However, for some applications, the recommendations of use of a product may differ and therefore additional test conditions need to be used.

1 Scope

This European Standard 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”.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2 step 1 test.

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 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal, mycobactericidal, sporicidal and fungicidal activity*

EN 14885:2006, *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 14885:2006 apply.

4 Requirements

The product shall demonstrate at least a 5 decimal log (lg) reduction 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 other obligatory test conditions (four selected test organisms, 20 °C, 5 min or 1 min (for hands disinfection)).

The bactericidal activity shall be evaluated using the following four test organisms:

- *Pseudomonas aeruginosa*;
- *Escherichia coli*;