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I.S. EN 1276:2009

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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1276:2009/AC

August 2010
Août 2010
August 2010

ICS 71.100.35

English version
Version Française
Deutsche Fassung

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 corrigendum becomes effective on 11 August 2010 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 11 août 2010 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 11.August 2010 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Ref. No.:EN 1276:2009/AC:2010 D/E/F

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1 Modification to 5.7.3, Basic limits

Replace the existing text:

"

For each test organism check that:

a) N is between $1{,}5 \cdot 10^7$ and $5{,}0 \cdot 10^7$ ($7{,}17 \leq lg\ N \leq 7{,}70$)

N0 is between $1{,}5 \cdot 10^6$ and $5{,}0 \cdot 10^6$ ($6{,}17 \leq lg\ N0 \leq 6{,}70$)

b) Nv0 is between 30 and 160 ($3{,}0 \cdot 10^1$ and $1{,}6 \cdot 10^2$)

(*Nv* is between $3{,}0 \cdot 10^2$ and $1{,}6 \cdot 10^3$)

c) *A,B,C* are equal to or greater than $0{,}5 \cdot Nv0$.

d) control of weighted mean counts (**5.7.2**): quotient is not lower than 5 and not higher than 15.

"

with the following (change back into the text as launched into UAP – only exception and additional change "8,18" *in a) replaced with* "8,17" *and* "7,18" *in a) replaced with* "7,17"*):*

"

For each test organism check that:

a) N is between $1{,}5 \times 10^8$ and $5{,}0 \times 10^8$ ($8{,}17 \leq \lg N \leq 8{,}70$);

N_0 is between $1{,}5 \times 10^7$ and $5{,}0 \times 10^7$ ($7{,}17 \leq \lg N_0 \leq 7{,}70$);

b) Nv_0 is between 30 and 160 ($3{,}0 \times 10^1$ and $1{,}6 \times 10^2$);

(Nv is between $3{,}0 \times 10^2$ and $1{,}6 \times 10^3$);

c) A, B, C are equal to or greater than $0{,}5 \times Nv_0$;

d) control of weighted mean counts (5.7.2): quotient is not lower than 5 and not higher than 15.

".

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1276

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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.

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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.

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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.

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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*;

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