Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 14347:2005 sisaldab Euroopa standardi EN 14347:2005 ingliskeelset teksti.

Käesolev dokument on jõustatud 30.05.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 14347:2005 consists of the English text of the European standard EN 14347:2005.

This document is endorsed on 30.05.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

This document specifies a test method (phase 1) and the minimum requirements for sporicidal activity of chemical disinfectant or antiseptic products that form a homogeneous, physically stable preparation when diluted 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.

Scope:

This document specifies a test method (phase 1) and the minimum requirements for sporicidal activity of chemical disinfectant or antiseptic products that form a homogeneous, physically stable preparation when diluted 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.

ICS 11.080.20, 71.100.35

Võtmesõnad: definitions, disinfectant tests, disinfectants, disinfection, disinfections, domestic, effects, efficiency, human medicine, hygiene, medical sciences, medicine, specification (approval), specifications, spores, testing, veterinary medicine, veterinary science

EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14347

March 2005

ICS 11.080.20; 71.100.35

English version

Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1, step 1)

Désinfectants chimiques - Activité sporicide de base - Méthode d'essai et exigences

Chemische Desinfektionsmittel und Antiseptika - Sporizide Wirkung (Basistest) - Prüfverfahren und Anforderungen (Phase 1, Stufe 1)

This European Standard was approved by CEN on 8 December 2004.

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.

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 Central Secretariat has the same status as the official versions

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

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Foreword

This document (EN 14347:2005) 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 September 2005, and conflicting national standards shall be withdrawn at the latest by September 2005.

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.

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, ay, 1 Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This document describes a suspension test for establishing whether a chemical disinfectant or antiseptic has or does not have a sporicidal activity in the areas described in the scope.

If a product complies with the test requirements, it can be considered as possessing a sporicidal activity. The acceptibility of a product as a chemical disinfectant or antiseptic for a defined purpose cannot be determined from this test method. Chemical disinfectants or antiseptics are subjected to further testing by relevant tests va.

, used in .

One of the control according to European Standards to evaluate their activity under conditions appropriate to their intended use.

There is no evidence that the strains used in this document are virulent.

1 Scope

This document specifies a test method (phase 1) and the minimum requirements for sporicidal activity of chemical disinfectant or antiseptic products that form a homogeneous, physically stable preparation when diluted 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.

This document applies to products that are used in agricultural (but not crop protection), domestic service, food hygiene and other industrial fields, institutional, medical and veterinary applications.

NOTE 1 This method cannot be applied for testing sporicidal activity of a product against spores of Clostridium sp.

NOTE 2 This document does not evaluate the activity of a product for an intended use. More specific test methods described in European Standards (see Introduction) are used for further assessement of the efficacy of chemical disinfectants and antiseptics for a defined purpose.

NOTE 3 This method corresponds to a phase 1 test (Annex E).

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 microbial strains used for the determination of bactericidal and fungicidal activity

EN 14079, Non-active medical devices – Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

product (for chemical disinfectants and/or antiseptics)

chemical agent or formulation used as chemical disinfectant or antiseptic

3.2

sporicide

product which kills dormant bacterial spores of relevant test organisms under defined conditions

NOTEThe adjective derived from "sporicide" is "sporicidal"

3.3

sporicidal activity

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

3.4

sporistatic activity

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