

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

The European Standard EN 12353:2006 has the status of a
British Standard

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National foreword

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Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal, sporicidal and fungicidal activity

Antiseptiques et désinfectants chimiques - Conservation des organismes test utilisés pour la détermination de l'activité bactéricide, mycobactéricide, sporicide et fongicide

Chemische Desinfektionsmittel und Antiseptika - Aufbewahrung von Testorganismen für die Prüfung der bakteriziden, mykobakteriziden, sporiziden und fungiziden Wirkung

This European Standard was approved by CEN on 23 February 2006.

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Foreword

This European Standard (EN 12353:2006) 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of an identical text or by endorsement, at the latest by December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

This European Standard supersedes EN 12353:1999.

It was revised to include mycobacteria and spore-forming bacteria and to harmonize the structure and wording with other CEN/TC 216 standards.

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

Introduction

Standardized tests for the determination of bactericidal, mycobactericidal, sporicidal and fungicidal activity of chemical disinfectants and antiseptics necessitate the use of test organisms whose purity and identity have been verified and whose biological behaviour remains stable. Therefore it is essential to specify the storage requirements.

This European Standard aims at describing methods for preservation of test organisms used for such purposes.

1 Scope

This European Standard specifies methods for keeping test organisms used and defined in European Standards for the determination of bactericidal, mycobactericidal, sporicidal and fungicidal activity of chemical disinfectants and antiseptics drawn up by CEN/TC 216. These methods for keeping test organisms can only be carried out in connection with at least one of those standards where a reference to this standard is established.

NOTE 1 Annex A (informative) contains a non-exhaustive list of test organisms for which this standard can be applied.

NOTE 2 European Standards (EN and prEN) where this European Standard is referenced are listed in the Bibliography.

2 Normative references

The following referenced documents are indispensable for the application of this European Standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4793, *Laboratory sintered (fritted) filters – Porosity grading, classification and designation*.

3 Terms and definitions

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

3.1

bactericidal activity

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

3.2

conidium

asexual fungal spore, produced exogenously from a hyphal tip

NOTE Conidiospore is a synonym for conidium.

3.3

fungicidal activity

capability of a product to produce a reduction in the number of viable vegetative yeast cells and mould spores of relevant test organisms under defined conditions

3.4

mycobactericidal activity

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

3.5

product

chemical agent or formulation used as a chemical disinfectant or antiseptic

3.6

sporicidal activity

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

3.7

test organism

strain of a micro-organism selected for testing products within a standardized test

NOTE For the purpose of this European Standard the term micro-organism includes vegetative bacteria, bacterial spores, fungi, fungal spores and viruses.

3.8

yeastocidal activity

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

4 Requirements

Each test organism specified in a CEN/TC 216 European Standard and referred to in this standard shall be handled as described in this standard.

The purity and identity of the preserved test organism shall be verified during the preparation and regularly during the storage.

The preserved test organism should be checked at regular intervals (at least in the case of longer storage than 14 months) to ensure that its susceptibility to products has not changed. As long as CEN/TC 216 has not developed specific tests for this purpose any suitable method can be used e.g. EN 1040 for bacteria, EN 1275 for fungi or EN 14348 for mycobacteria.

5 Methods

5.1 Principle

A freeze dried sample of the test organism is obtained from a culture collection. This sample is cultured, prepared for storage, filled into storage vessels and placed in the deep freeze.

From the deep freeze samples a stock culture is prepared and subsequently used to prepare working cultures for the test procedure. In some cases the working cultures are directly prepared from the deep freeze samples.

5.2 Materials and reagents

5.2.1 Test organisms

See Annex A for examples of test organisms.

The origin (culture collection), taxonomic name and reference number, date of receipt and batch number of the freeze dried test organisms shall be recorded (**5.9.2**).

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this European Standard 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.