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Irish Standard
I.S. EN 12353:2013

Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12353

February 2013

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Supersedes EN 12353:2006

English Version

Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

Antiseptiques et désinfectants chimiques - Conservation des organismes test utilisés pour la détermination de l'activité bactéricide (Legionella inclus), mycobactéricide, sporicide, fongicide et virucide (bacteriophages inclus)

Chemische Desinfektionsmittel und Antiseptika - Aufbewahrung von Testorganismen für die Prüfung der bakteriziden (einschließlich Legionella), mykobakteriziden, sporiziden, fungiziden und viruziden (einschlißlich Bakteriophagen) Wirkung

This European Standard was approved by CEN on 14 December 2012.

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Foreword

This document (EN 12353:2013) 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of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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 12353:2006.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities. The following are the significant technical changes since the last edition:

— The methods of preservation of Legionella, mycobacteria, bacteriophages and viruses are new and were added. Data obtained by using the former version of EN 12353 are still valid.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Introduction

Standardized tests for the determination of bactericidal (incl. *Legionella pneumophila*), mycobactericidal, sporicidal, fungicidal and virucidal (incl. bacteriophages) 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.

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1 Scope

This European Standard specifies methods for keeping test organisms used and defined in European Standards for the determination of bactericidal (incl. *Legionella pneumophila*), mycobactericidal, sporicidal, fungicidal and virucidal (incl. bacteriophages) 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 European 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.

NOTE 3 A specific part on the preservation of bacterial spores may be added once the results of the ongoing ring trials are available.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 14885, *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 apply.

4 Requirements

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

The purity and identity of the preserved test organism shall be verified during the preparation and regularly during the storage, except for viruses where only the identity is checked before the stock virus suspension is stored.

The preserved test organism – except viruses - 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, EN 14348 for mycobacteria, EN 13623 for *Legionella pneumophila*, EN 14476 for viruses or EN 13610 for dairy bacteriophages.

5 Methods

5.1 Principle

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

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