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NSAI Standards

Irish Standard
I.S. EN 12353:2021

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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National Foreword

I.S. EN 12353:2021 is the adopted Irish version of the European Document EN 12353:2021, 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

September 2021

ICS 11.080.20; 71.100.35

Supersedes EN 12353:2013

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 micro-organismes d'essai utilisés pour la détermination de l'activité bactéricide (Legionella incluses), mycobactéricide, sporicide, fongicide et virucide (bactériophages inclus)

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

This European Standard was approved by CEN on 1 February 2021.

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European foreword

This document (EN 12353:2021) 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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12353:2013.

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 viruses are described more detailed (5.8);

— MEM is not the only suitable cell culture medium, therefore it was replaced by the general term "cell culture medium" (5.2.2.17 and in the whole text);

— the description of BCYE Agar for *Legionella* was added (5.2.2.24);

— the information on source of strains was added (5.10.2);

— the information of the storage of documentation was added (5.11.6);

— *Clostrioides difficile* (A.3.3) was added;

— the CIP numbers for fungi were deleted (replaced by UMIP numbers) (see A.4);

— the used virus strains are re-drafted (see A.5).

The changes mentioned above have no impact on the test results obtained with reference to the previous version. Those results are still valid.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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 document aims to describe methods for preservation of test organisms used for such purposes.

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1 Scope

This document 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 document is established.

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

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 13610, *Chemical disinfectants — Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas — Test method and requirements (phase 2, step 1)*

EN 14885, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

4 Requirements

Each test organism specified in a CEN/TC 216 European Standard and referred to in this document shall be handled as described in this document. An overview of the CEN/TC 216 standards and the specification of which standards products shall comply with in order to support specific microbicidal activity claims are summarised in EN 14885.

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 organisms – including the viruses especially in connection with the used cell lines - 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. For all standards where there is no internal standard implemented the test organisms' susceptibility should be checked using relevant reference substances.

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