Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities

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NATIONAL FOREWORD

See Eesti standard EVS-EN 17272:2020 sisaldab Euroopa standardi EN 17272:2020 ingliskeelset teksti.	This Estonian standard EVS-EN 17272:2020 consists of the English text of the European standard EN 17272:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 08.04.2020.	Date of Availability of the European standard is 08.04.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities

Antiseptiques et désinfectants chimiques - Méthodes de désinfection des pièces par voie aérienne par des procédés automatisés - Détermination de l'activité bactéricide, fongicide, levuricide, sporicide, tuberculocide, mycobactéricide, virucide et phagocide

Chemische Desinfektionsmittel und Antiseptika - Verfahren zur luftübertragenen Raumdesinfektion durch automatisierte Verfahren - Bestimmung der bakteriziden, mykobakteriziden, sporiziden, fungiziden, levuroziden, viruziden, tuberkuloziden, und Phagen-Wirksamkeit

This European Standard was approved by CEN on 13 October 2019.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 17272:2020) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2020, and conflicting national standards shall be withdrawn at the latest by October 2020.

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 describes a Phase 2 step 2 method designed:

— to check, under standardized laboratory conditions close to real-world practice, that the proposed airborne surface disinfection processes meet the objective for which they were devised;

— to cross-compare different processes under reproducible conditions;

— to provide an experimental design within specified limits when real-world-practice conditions depart from the conditions given in the text below.

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.

Introduction

The purpose of this document is to describe a test method for assessing the disinfectant activity of airborne surface disinfection processes under a specific experimental condition.

The proposed test method consists of 2 parts:

— Part 1 - Efficacy test: intended to ensure that minimum efficacy requirements are fulfilled for each type of activity claimed and for the targeted application area(s) (CEN/TC 216 WG 1 and/or WG 2 and/or WG 3).

— Part 2 - Distribution test: intended to ensure efficacy of the process throughout the enclosure. It is performed with a reference test organism at 4 sampling positions.

The processes concerned include those involving chemical disinfectants in dispersed gaseous, vapour and/or aerosolised form.

Every automated airborne disinfection cycle/application is unique and the purpose of this document is to provide a defined challenge for the automated airborne disinfection system to successfully meet in order to be considered an efficacious process. This standard method should therefore be regarded as a useful starting point and not as a validation for all intended treatments with a particular automated airborne disinfection system.

The method is used to qualify the process, i.e. the device(s) and product(s) needed for implementation. For such chemical processes, the combination of device and product cannot be separated.

For the defined test conditions the number of carriers and their test positions can be increased according to specific needs of a given application or local requirements.

The manufacturer:

— specifies the limitations and precautions for use of the process;

— ensures that the specified test conditions are representative for the recommended application(s).

The aim of this document is to simulate practical conditions of airborne disinfection in a laboratory situation; obligatory conditions are defined according to the test method defined below. Additional conditions are also proposed.

The test report specifies and summarizes the conditions under which the tests are carried out.

Generally, the processes are implemented after a cleaning procedure and then tested, according to the application areas, under clean or low-level soiling conditions. For specified applications and/or according to the manufacturer recommendations, test methods with other interfering substance can also be envisaged as additional conditions.

The tests described in this document are based on measuring the reduction (expressed as decimal logarithm lg) in terms of numbers of surviving test organisms of different strains of bacteria, mycobacteria, bacterial spores, fungal spores, yeasts, viruses or bacteriophages and under specified conditions. Test organisms may be supplemented by other test organisms. The experimental design described in this document is expected to be followed, but the conditions can be varied according to the needs of the practical application(s).

This method can be used as a basis for biosecurity applications in laboratories.

CEN/TC 216 phase 2, step 1 suspension tests for evaluating the irreversible inactivation by the product cannot be performed as the product is changed by the diffusion through the air (e.g. liquid state vs vapour state).

1 Scope

The test methods described are designed to determine the disinfectant activity of processes used in the 1) medical area, 2) veterinary area, 3) food, industrial, domestic and institutional area using automated processes for distributing chemicals by air diffusion with no operator manually applying the disinfectant. This document covers the disinfection of nonporous surfaces but not that of the air.

The objective of the described processes is to disinfect the surfaces of the overall area including the external surfaces of the equipment contained in such rooms. Air handling and products or processes specifically designed for the disinfection of medical devices are excluded from the scope of this document. The test methods and volumes described provide a defined challenge.

This document is applicable to processes for which activity is claimed against the following groups of microorganisms:

— vegetative bacteria,

— mycobacteria,

— bacterial spores,

— yeasts,

— fungal spores,

— viruses,

— bacteriophages.

This document does not cover processes for which the mode of action is based on immersing and/or circulation, flooding, spraying, wiping or other processes where the product is directly applied to the surfaces and not via air dispersion.

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 10088-2, *Stainless steels —Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

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