ICS 11.080.20 SLOVENSKÁ TECHNICKÁ NORMA December 2019

STN	**Chemické dezinfekčné a antiseptické prípravky Kvantitatívna skúška na vyhodnotenie virulocídnej aktivity pre chemické dezinfekčné a antiseptické prípravky používané v oblasti medicíny Skúšobná metóda a požiadavky (fáza 2, krok 1)**	**STN EN 14476+A2** 85 7029

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/19

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Oznámením tejto normy sa ruší
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EN 14476:2013+A2

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English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)

Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l¿évaluation de l¿activité virucide dans le domaine médical - Méthode d¿essai et prescriptions (Phase 2/Étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 27 July 2015 and includes Amendment 2 approved by CEN on 9 April 2019.

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

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European foreword

This document (EN 14476:2013+A2:2019) 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identical text or by endorsement, at the latest by [A2] January 2020 [A2] and conflicting national standards shall be withdrawn at the latest by [A2] January 2020 [A2].

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 [A2] EN 14476:2013+A1:2015 [A2].

This document includes Amendment 1 approved by CEN on 2015-07-27 and Amendment 2 approved by CEN on 2019-04-09.

The start and finish of text introduced or altered by amendment 1 is indicated in the text by tags [A1] [A1].

The start and finish of text introduced or altered by amendment 2 is indicated in the text by tags [A2] [A2].

[A1] This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document. [A1]

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonise the structure and wording with other existing tests of CEN/TC 216 or in preparation and to improve the readability of the standard and thereby make it more understandable. The following list is a list of significant technical changes since the last edition:

- The scope was expanded for the following fields of application within the medical area, i.e. products for textile disinfection.
- “Obligatory test conditions” were replaced by “minimum test conditions” (test temperatures and contact times can be chosen within limits) that have to be performed to pass the test.
- An additional modified method is described to test ready-to-use products in a higher concentration than 80 %, i.e. 9 7%;

[A1]

- For the hygienic handrub and handwash method a test for virucidal activity against enveloped viruses with *Vacciniavirus* was added.
- The relationship between this European Standard and the MDD was added (Foreword and Annex ZA).
- The value of v_n in C.1 was corrected (0,001 instead of 0,0001). [A1]

[A2] • For the surface disinfection a test for virucidal activity against enveloped viruses with vaccinia virus was added and a test for limited spectrum virucidal activity with adenovirus and murine norovirus was added;

- The spelling of Vaccinavirus is corrected to vaccinia virus (Table 1);
- The limited spectrum virucidal activity will cover norovirus, rotavirus and adenovirus;
- The vaccinia virus strain Elstree was added as alternative strain [5.2.1c)1)], [5.5.1.1.e)];
- For dirty conditions (5.2.2.8.3) the resuspension shall be done in PBS and not in water (editorial change reflecting the actual practice);
- the dilution in ice-cold medium for the control of efficiency of suppression of products activity (5.5.5.1) was clarified;
- addition of the large-volume-platting method (5.5.4.3, B.3) [A2]

[A2] The changes mentioned above have no impact on the test results obtained with reference to the previous version. Those results are still valid. [A2]

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical area are in preparation.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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 Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a virucidal activity in the area and fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence its action in practical situations. Each utilisation concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.

1 Scope

This European Standard specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i. e, products that are not diluted when applied,– with water. Products can only be tested at a concentration of 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European Standard applies to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities, and in dental institutions;

— in clinics of schools, of kindergartens, and of nursing homes;

and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test.

NOTE 3 EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

2 Normative references

A2 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. A2

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*