Irish Standard
I.S. EN 14476:2013+A2

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)

I.S. EN 14476:2013+A2

Incorporating amendments/corrigenda/National Annexes issued since publication:

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This document is based on:	*Published:*
EN 14476:2013+A2	2019-07-17

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2019-08-04	11.080.20
	NOTE: If blank see CEN/CENELEC cover page

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National Foreword

I.S. EN 14476:2013+A2 is the adopted Irish version of the European Document EN 14476:2013+A2, 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)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14476

July 2019

ICS 11.080.20

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.

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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 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.