SLOVENSKI STANDARD

SIST EN 14476:2013/kFprA1:2015

01-junij-2015

Kemična razkužila in antiseptiki - Kvantitativni suspenzijski preskus za vrednotenje virucidnega delovanja v medicini - Preskusna metoda in zahteve (faza 2, stopnja 1)

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)

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

Ta slovenski standard je istoveten z: **EN 14476:2013/FprA1**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

SIST EN 14476:2013/kFprA1:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 14476:2013

FprA1

March 2015

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 draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 216.

This draft amendment A1, if approved, will modify the European Standard EN 14476:2013. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (EN 14476:2013/FprA1:2015) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Unique Acceptance Procedure.

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.

NOTE Due to fact that the EC has not yet been able to confirm the financial commitment for the New Approach Consultants’ work in 2015, there are currently no New Approach Consultants in place for 2015. Therefore the provisions of CEN-CENELEC Guide 15 cannot be met.

This shall not prevent the processing of draft standards nor the offering of harmonized standards to the European Commission. In particular, draft standards can be sent to vote without Consultant assessment.

This note will be removed from the Foreword of the finalized publication.

1 Modifications to Foreword

Add the following new paragraphs:

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, whichwhich is an integral part of this document.

Add the following to the existing list of modifications :

"• For the hygienic handrub and handwash method a test for virucidal activity against enveloped viruses with *Vacciniavirus* was added.

- The relationship between this Europaen 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).".

2 Modifications to Clause 4, Table 1

*In Table 1, 2nd column, 2nd line, add "*Virucidal activity against enveloped viruses*" and "Vacciniavirus", add new footnote b, "*The test for virucidal activity against enveloped virus will cover all enveloped viruses only (Annex A).*" and update footnote numbering to read as follows*:

"Table 1 — Minimum and additional test conditions

Test Conditions	Hygienic handrub and handwash	Instrument disinfection	Surface disinfection	Textile disinfection
Minimum spectrum of test organisms	*Poliovirus* *Adenovirus* *Murine Norovirus* **Limited spectrum virucidal activity**[a] *Adenovirus* *Murine Norovirus* **Virucidal activity against enveloped viruses** [b] *Vacciniavirus*	*Poliovirus* *Adenovirus* *Murine Norovirus* when temperature is 40 °C or higher: only *Parvovirus*	*Poliovirus* *Adenovirus* *Murine Norovirus*	*Parvovirus*
Additional	Any relevant test organism			
Test temperature	according to the manufacturer's recommendation, but at / between			
	20 °C	20 °C and 70 °C	4°C and 30 °C	30 °C and 70 °C
Contact time	according to the manufacturer's recommendation			
	but between 30 s and 120 s	but no longer than 60 min	but no longer than 5 min or 60 min [c]	but no longer than 20 min

Interfering substance				
clean conditions	0,3 g/l bovine albumin solution (hygienic handrub) [d]	0,3 g/l bovine albumin solution **and/or**	0,3 g/l bovine albumin solution **and/or**	
dirty conditions	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (hygienic handwash) [e]	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes
Additional conditions [e]	clean or dirty [d, e]; any relevant substance	any relevant substance	any relevant substance	any relevant substance

[a] The test for limited spectrum virucidal activity will cover all enveloped viruses (Annex A) and the specified test organisms .

[b] The test for virucidal activity against enveloped virus will cover all enveloped viruses only (Annex A).

[c] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, shall be tested with a contact time of maximum 5 min. The same applies where the contact time of the product shall be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

[d] Hygienic handrub shall be tested as a minimum under clean conditions.

[e] Hygienic handwash shall be tested as a minimum under dirty conditions.

[f] For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.

".

3 Modifications to 5.2.1

Add a new indent c):

"

c) Enveloped DNA virus

1) Vacciniavirus, strain Ankara (MVA), ATCC VR-1508.".

In footnote 2, correct "Bundesforschunsinstitut" *with* "Bundesforschungsinstitut".

4 Modification to 5.5.1.1

Add at the end of e) "*Vacciniavirus* is multiplied in BHK-21cells (ATCC CCL-10) or other cell lines of appropriate sensitivity." *to read:*

"

e) cell line(s):

Adenovirus is multiplied in HeLa cells or other cell lines of appropriate sensitivity

Poliovirus is multiplied in HeLa cells or other cell lines of appropriate sensitivity

Norovirus is multiplied in RAW 264.7 cells (ATCC TIB-71) or other cell lines of appropriate sensitivity

Parvovirus is multiplied in A9 cells (ATCC CCL-1.4) or other cell lines of appropriate sensitivity

Vacciniavirus is multiplied in BHK-21cells (ATCC CCL-10) or other cell lines of appropriate sensitivity.".

5 Modification to 5.5.4.1

Replace the 1st sentence in the 1st paragraph with the following:

"To check for possible morphological alteration of cells by the disinfectant, 1 part of hard water (5.2.2.7) and 1 part of interfering substance(s) (5.2.2.8) are mixed with 8 parts of the product test solution (5.4.2).".

6 Modification to 5.7

Replace indent b) with the following:

"b) difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test (5.5.6) is between –0,5 and –2,5 after 30 min and between –2 and –4,5 after 60 min for *poliovirus*; between –3 and –5 after 30 min and between –3,5 and –5,5 after 60 min for *adenovirus* and between 0,0 and –2,0 after 30 min and between –0,5 and –2,5 after 60 min for *parvovirus;* between –0,75 and –3,5 after 5 min and between –2,0 and ≥–4,0 after 15 min for *vacciniavirus*.".

7 Modification to C.1

In the key to Formula (C.1), value of v_n, *replace* "0,0001" *with* "0,001" *to read:*

"v_n is the dilution factor between n 1/ n n (e.g. n 1 = 10-3 and n n = 10-6, then vn = 0,001);".

8 Addition of an Annex ZA

Add the following new Annex ZA:

"