SLOVENSKI STANDARD
SIST EN 13727:2012+A1:2014/kFprA2:2015

01-junij-2015

Kemična razkužila in antiseptiki - Kvantitativni suspenzijski preskus za vrednotenje baktericidnega delovanja kemičnih razkužil in antiseptikov v humani medicini - Preskusna metoda in zahteve (faza 2, stopnja 1)

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der bakteriziden 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 bactéricide en médecine - Méthode d'essai et prescriptions (phase 2, étape 1)

Ta slovenski standard je istoveten z: **EN 13727:2012+A1:2013/FprA2:2015**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

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EUROPEAN STANDARD

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English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal 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 bactéricide en médecine - Méthode d'essai et prescriptions (phase 2, étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der bakteriziden 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 A2, if approved, will modify the European Standard EN 13727:2012+A1:2013. 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
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Foreword

This document (EN 13727:2012+A1:2013/FprA2:2015) 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 93/42/EEC.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

1 Modification to 5.5.2.2 d)

Replace the existing text of 5.5.2.2, item d), with the following:

"d) Additionally transfer 0,5 ml of this mixture into a tube containing 4,5 ml of neutralizer to obtain 10^{-1} dilution of N_a, with hygienic handwash products mix and dilute additionally with neutralizer to obtain a 10^{-2} dilution of N_a. Take samples of 1,0 ml from each dilution tube in duplicate and inoculate using the pour plate or spread plate technique.

In the case of hygienic handwash products you may inoculate and incubate only the 10^{-2} dilution of N_a and not the 10° [see 5.5.2.2 c)] and the 10^{-1} dilution.

For incubation and counting, see **5.5.2.6**."

2 Modification to 5.5.2.4 a), NOTE

Replace the existing text of 5.5.2.4 a) NOTE with the following:

"NOTE The high amount of neutralizer in relation to the test organisms reflects the additional dilutions with neutralizer – in the case of N_a [**5.5.2.2 d)**] 10^{-1} and for hygienic handwash products10^{-1} and 10^{-2}."

3 Modification to 5.5.3.2

Replace the existing text of 5.5.3.2 with the following:

"

a) See 5.5.2.2 a) and b)

b) At the end of *t*, take a sample of 0,1 ml of the test mixture N_a (for hygienic hand wash products 1 µl) in duplicate and transfer each 0,1 ml (1 µl) sample into a separate membrane filtration apparatus (**5.5.3.1**). Filter immediately. Filter through at least 150 ml but no more than 500 ml of rinsing liquid (**5.2.2.6**). If the rinsing liquid is not water, complete the procedure by filtering 50 ml of water (**5.2.2.2**). Then transfer each of the membranes to the surface of separate TSA plates.

NOTE The amount of 1 µl takes into account the 100 fold dilution of N_a [10^{-2} dilution in **5.5.2.2** d)] which enables the measurement of a 3 lg reduction. Since it is not recommended to pipette microbial suspensions in 1 µl portions, you may dilute for example 1 ml in 1 000 ml rinsing liquid (or 100 µl in 100 ml) beforehand and pour 1 ml of this mixture into the membrane filtration apparatus."

4 Modification to 5.6.2.2 b)

Replace the text of 5.6.2.2 b) with the following:

"

b) For counting the test suspension N (**5.4.1.6**), the validation suspensions N_V and N_{VB} (**5.4.1.6**) and for all countings of the dilution-neutralization method (**5.5.2.6**), determine and record the V_C-values according to the number of plates used per 1 ml (or other volumes for membrane filtration and/or hygienic handwash products) sample (**5.6.1.2**)."

5 Modifications to 5.6.2.4 a) and Examples a1 and a2

Replace the first sentence of 5.6.2.4 a) with the following:

"

a) Calculate the mean for each dilution step $N_a^{\ 0}$, $N_a^{\ -1}$ and for hygienic handwash products additionally $N_a^{\ -2}$ using the following formula:"

Replace the existing text of the Examples a1 and a2 with the following:

"

EXAMPLES

a1 duplicate V_C-values $N_a^{\ -1}$: 2, 16

$$N_a^{-1} = \frac{(< 14 + 16) \times 10}{2} \times 10^1 = < 150 \times 10^1 = < 1500 = < 1{,}5 \times 10^3$$

In this case the number is between 8.000 and 14.500.

a2 duplicate V_C-values $N_a^{\ -2}$ (membrane filtration): >165, >165

$$N_a^{-2} = \frac{(> 165 + > 165) \times 10}{2} \times 10^2 = > 1650 \times 10^2 = > 165\,000 = > 1{,}65 \times 10^5$$

"

6 Modifications to 5.6.2.4 b), NOTE and Example b1

Replace the existing text of 5.6.2.4 b), the NOTE and ***b1*** *with the following:*

"b) For calculation of N_a use only $N_a^{\ 0}$, $N_a^{\ -1}$, $N_a^{\ -2}$ results, where one or both V_C-values are within the counting limits. Exceptions and rules for special cases:

NOTE Although 10^{-2} dilutions are only prepared when hygienic handwash products are tested, the following examples include this dilution step.

b1 If all subsequent dilutions of N_a show mean values of „more than", take only the highest dilution (10^{-1}, with hygienic handwash products 10^{-2}) as result for N_a."

7 Modification to 5.6.2.4 b), Example b2

Replace the existing text of 5.6.2.4 b) ***b2*** *with the following:*

"b2 If all subsequent dilutions of N_a show mean values of „less than", take only the lowest dilution (10^0) as result for N_a.

EXAMPLE 2

	V_{C1}	V_{C2}	mean x 10	
$N_a^{\ 0}$	< 14	18	< 160	N_a = < 160 x 10^0 = < 1,6 x 10^2
$N_a^{\ -1}$	< 14	< 14	< 140	
$N_a^{\ -2}$	< 14	< 14	< 140	

In this case the number is between 90 and 155."

8 Modification to 5.8.3

Replace the existing text of 5.8.3 with the following:

"For each test organism, record the lowest concentration of the product which passes the test (lg $R \geq 5$ or for hygienic handwash products lg $R \geq 3$). Record as the limiting test organism the test organism requiring the highest of these concentrations (it is the least susceptible to the product in the chosen experimental conditions). "

9 Modification to 5.8.4

Replace the 2nd paragraph of 5.8.4 with the following:

"Repetition means the complete test procedure with separately prepared test - and validation suspensions. The repetitions may be restricted to the limiting test organism. The mean (i.e. before logarithmation) of the results of the repetitions - not each single result - shall demonstrate at least a 5 lg reduction (in the case of hygienic handwash products 3 lg) and shall also be calculated and recorded."