SLOVENSKI STANDARD
SIST EN 17272:2020/oprA1:2023

01-december-2023

Kemična razkužila in antiseptiki - Metode za dezinfekcijo površin v prostorih z delci v zraku z avtomatiziranim postopkom - Določevanje baktericidne, mikobaktericidne, sporocidne, fungicidne, virucidne, tuberkulocidne in fagocidne aktivnosti ter aktivnosti kvasovk - Dopolnilo A1

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

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

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 phagocid

Ta slovenski standard je istoveten z: **EN 17272:2020/prA1**

ICS:

11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics
71.100.35	Kemikalije za dezinfekcijo v industriji in doma	Chemicals for industrial and domestic disinfection purposes

SIST EN 17272:2020/oprA1:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN 17272:2020

prA1

November 2023

ICS

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 phagocid

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

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

This draft amendment A1, if approved, will modify the European Standard EN 17272:2020. 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.

CEN members are the national standards bodies of 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, Türkiye and United Kingdom.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN 17272:2020/prA1:2023) 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 CEN-Enquiry

This document will supersede EN 17272:2020.

A significant number of the modifications listed in this amendment are editorial and the result of re-ordering the text within the standard. To allow users to quickly ascertain and understand the key technical amendments and / or clarifying text that have been introduced to EN 17272, the modifications have been listed in two sections. The first section presents the sections with fundamental technical changes driven by the amendment and the second section the solely editorial amendments.

1 Technical amendments

1.1 Modifications to the Foreword

Add in the end the following sentence:

"Results obtained using the 2020 version of the standard prior to the amendment remain valid."

1.2 Modification to 5.2.2.2.8 (old) to 5.2.2.2.7 (new)

Replace the reference behind Tryptone salt with "(5.2.2.2.7)" and add in the last paragraph the following sentence:

"In this case, water (5.2.2.2.1) can be used as diluent."

Change "Bacteria, fungi, yeast and spores" to "Bacteria, yeast, fungi and spores"

1.3 Modification to 5.2.2.2.9 (old) to 5.2.2.2.8 (new)

Add in the list of composition 5,0 g polysorbate 80 *and also in the preparation.*

Add in the end a sentence for viruses. The whole modification reads as follows:

"Composition:

Tryptone, pancreatic digest of casein	1,0 g
Sodium chloride	8,5 g
Polysorbate 80	5,0 g
Water (see 5.2.2.2.1) to	1.000,0 ml

Preparation:

Dissolve the sodium chloride and tryptone in the water. Add polysorbate 80 and any neutralizing agent specifically designed for the product under test.

Prepare the diluent in large-volume batches, then distribute into smaller adapted flasks. Sterilize in the autoclave.

For mycobacteria, water (refer to 5.2.2.2.1) is used instead of diluents.

For viruses, preservation media (refer to 5.2.2.3.1) is used instead of diluents."

1.4 Add new paragraph 5.2.2.4.8

Add the following new paragraph:

"5.2.2.4.8 Bacteriophage and virus recovery and rinsing liquid

For bacteriophage and virus, growth and preservation media (5.2.2.3.1) are used."

1.5 Modification to 5.4.2.1 (old) 5.4.1.3.1. (new)

In the last paragraph replace "10^8" with "10^9", to read:

"Increase the initial inoculum up to 5×10^9 and add to the interfering substance a 1/20 dilution rate of skimmed milk."

1.6 Modification to 5.5.1.2.1

Replace existing text with

*"*To be run in parallel with the efficacy and distribution tests*"*

1.7 Modification to 5.5.1.4.2

Replace

"Distribute the three carriers strain-by-strain at a height (H) in the range 1 to 1,5 m and at a distance (D) as defined in the table in Annex B according to the volume of the enclosure.

Position of the carriers: vertical.

Orientation: microbial inoculum facing away from the release source."

with

"Distribute the carriers strain-by-strain in accordance with Annexes A and B.

For the efficacy test:

Position of the carriers: vertical.

Orientation: microbial inoculum facing away from the release source.

For the distribution test:

Position and orientation of the carriers shall be in accordance with Annex A (also see Figures E.5, E.6 and E.7)

NOTE The position of the diffusion device remains identical for the efficacy and distribution tests. The distance from the diffusion device to each carrier in the distribution test is not expected to be equal."

1.8 Modification to 5.5.2.2.1c)

Replace

"Once the ADC time and the ensuing aeration time, if applicable, have elapsed, recover the carriers and transfer them to 20 ml of recovery liquid to neutralize the action of the product.

This gives the recovery solution S.

Neutralization by means of dilution effect or by adding a specific agent should be explained in the report.

Incomplete neutralization of the residue shall invalidate the tests."

with

"Once the ADC time and the ensuing aeration time, if applicable, have elapsed, recover the carriers and transfer them to 20 ml of recovery liquid (refer to 5.2.2.2.9) to neutralize the action of the product.

The quantity of recovery liquid may be reduced provided that its neutralizing potential remains adequate.

This gives the recovery solution S."

1.9 Addition of new 5.5.2.2.2

Add after new 5.5.2.2.1 the following new paragraph:

"5.5.2.2.2 Cytotoxicity

Solution S is diluted from 10-1 to 10-4.

Cell treatment:

a) Cell monolayer: 0,1 ml of solution diluted from 10-1 to 10-4 is dispensed on adherent cells into each well of the 96-well microplate.

b) Suspended cell: 0,1 ml of solution diluted from 10-1 to 10-4 is dispensed into each well of the 96-well microplate. 0,1 ml of cell suspension and incubate at (37 ± 1) °C.

In case of residual cytotoxicity, the residual infectivity titre shall be ≥ 4,5 lg."

1.10 Modification to 5.5.2.2.2 (old) 5.5.2.2.3 (new)

Replace the first paragraph with the following two paragraphs:

"The reduction in susceptibility of the cells to viruses is evaluated by means of comparative titres of the virus on cells treated or not treated with the lowest non-cytotoxic dilution of the product:

A volume of solution S is added to 9 volumes of recovery liquid (refer to 5.2.2.2.9). In case of residual cytotoxicity, solution S must be diluted to identify the lowest non-cytotoxic dilution."

1.11 Modification to 5.5.2.2.2 a) (old) 5.5.2.2.3 a)(new)

Add "diluted" *before "*solution*", to read*:

"a) cell monolayer: 0,1 ml of diluted solution S or PBS is dispensed into..."

1.12 Modification to 5.5.2.2.2 b) (old) 5.5.2.2.3 b)(new)

Replace the paragraph b) with the following:

"b) suspended cells: one volume of diluted solution S or PBS is added to one volume of double concentrated cell suspension. After 1 h at (37 ± 1) °C, the cells are centrifuged and resuspended in two volumes of culture medium."

1.13 Modification to 5.5.2.2.2 (old), 5.5.2.2.3 (new), Comparative virus titre

*Replace the three paragraphs of the description of "*comparative virus titre*" with the following:*

"The virus suspension is diluted from 10−1 to 10−10 and titrated on the treated and untreated cells in parallel.

a) Using cell monolayer: Transfer 0,1 ml of each virus dilution in six or eight wells of the 96-well microplate with the treated or untreated cell monolayer, beginning with the highest dilution. The last row of six or eight wells will receive 0,1 ml of culture medium and will serve as the cell control. After 1 h of incubation at (37 ± 1) °C, 0,1 ml of cell maintenance medium is added to each well.

b) Using suspended cells: Transfer 0,1 ml of each dilution in six or eight wells of the 96-well microplate, beginning with the highest dilution. Add 0,1 ml of the treated or untreated cells into the six or eight wells of the 96-well microplate.

There is no loss of susceptibility when solution S induces a reduction of the virus titre < 1 lg compared to PBS."

1.14 Modification to 5.5.2.2.3 (old), 5.5.2.2.4 (new)

Replace the entire clause with:

"A volume of solution S (or PBS as control) is to be added to 1 volume of virus suspension. After 30 min at (20 ± 1) °C, a series of dilutions is prepared and the viral titres are compared.

The difference between the titres shall not exceed 0,5 lg.

Neutralization by means of dilution effect or by adding a specific agent should be explained in the report.

Incomplete neutralization of the residue shall invalidate the tests."

1.15 Modification to 5.5.2.4

*Addition of "*PFU/ml*" after 1 x 10^7 and 1 x 10^9*

Replace "<" *with* "≤", *to read*:

"d) neutralization test: difference between tests and controls ≤ 0,5 lg.

Delete "All the results are reported as raw data and are further presented as negative TCID50 or PFU values"

1.16 Modification to 5.6

Change the order of the title to "Bacteria, mycobacteria, bacterial spores, yeasts, fungal spores and bacteriophages".

Add "This chapter applies for efficacy test and distribution test"

1.17 Modification to 5.6.3

Modify the Example to read:

$$N = \frac{233 + 215 + (27 + 21)}{2{,}2} \times 10^6 = 205{,}8 \times 10^6 = 21{,}1 \times 10^8 \text{ microorganisms/ml}$$

1.18 Modification to 5.6.6

Add an explanation behind the first bullet point, to read:

"— either from the filtration of 87 ml of recovery liquid (by applying the rule of three: (number of colonies for 87 ml / 87) x 100);"

1.19 Modification to 5.7

Replace the first paragraph as follows:

"number of the working culture suspensions: *N* shall be in the range 5 × 10^7 to 2 × 10^9 cfu/ml for bacteria (see 5.2.1.1 to 5.2.1.6) expected for *P. aeruginosa* (5 × 10^7 to 5 × 10^9 cfu/ml), between 1 × 10^7 and 1 × 10^8 CFU/ml for mycobacteria (refer to 5.2.1.7 and 5.2.1.8), between 2 × 10^5 and 5 × 10^5 cfu/ml (2 × 10^6 and 5 × 10^6 cfu/ml for medical area) for the *Bacillus subtilis* spores (refer to 5.2.1.9), between 2 × 10^7 and 1 × 10^8 cfu/ml for *Candida albicans* (refer to 5.2.1.10), between 5 × 10^6 and 1 × 10^7 cfu/ml for *Aspergillus brasiliensis* (5.2.1.11), between 8 × 10^8 and 3 × 10^9 PFU/ml for bacteriophages (refer to 5.2.1.15 and 5.2.1.16) and between 1 × 10^7 and 1 × 10^9 PFU/ml for viruses (refer to 5.2.1.12, 5.2.1.13 and 5.2.1.14)"

After "* Minimum lg reduction required to pass standard: refer to Annex A", *add the following:*

"Each activity can be claimed independently but bactericidal and yeasticidal activities are the minimum to be passed.

An activity for a group of microorganisms (e.g. virucidal) can only be claimed for the concerned area if all specified microorganisms of this group have been successfully tested."