SLOVENSKI STANDARD
kSIST-TP FprCEN/TR 18010:2023

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Kemična razkužila in antiseptiki - Informacije o pripravi spor in določanju/izključevanju sporistatične aktivnosti

Chemical disinfectants and antiseptics - Information on the preparation of spores and determination/exclusion of sporistatical activity

Chemische Desinfektion und Antiseptika - Informationen zur Aufbereitung von Sporen und Bestimmung/Abgrenzung der sporistatischen Wirkung

Antiseptiques et désinfectants chimiques - Informations sur la préparation des spores et détermination/délimitation de l'effet sporistatique

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TECHNICAL REPORT

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English Version

Chemical disinfectants and antiseptics - Information on the preparation of spores and determination/exclusion of sporistatical activity

Antiseptiques et désinfectants chimiques ¿ Informations sur la préparation des spores et détermination/délimitation de l'effet sporistatique

Chemische Desinfektion und Antiseptika - Informationen zur Aufbereitung von Sporen und Bestimmung/Abgrenzung der sporistatischen Wirkung

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

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European foreword

This document (FprCEN/TR 18010:2023) 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 the Vote on TR.

Introduction

In the past, spore production has led to the following problems:

Chemical susceptibility of *B. cereus* and *B. subtilis* spore suspensions prepared according EN 13704 and EN 17126 did not comply with the specified requirements/lg-reductions due to the lack of buffering of the glutardialdehyde. In the update version of EN 13704 a check of the chemical susceptibility for *C. sporogones* with reference substances is missing. Data for Glutardialdehyde (GA) and Peracetic acid (PAA) have to be collected and included in a revised EN 13704.

These can be avoided if the following notes and information are taken into account.

The chemical susceptibility test of *C. difficile* spore suspension at EN 17126 is unchanged and included for completeness of this technical report.

Also a test method to differentiate between sporicidal and sporistatical activity of a product, which is included in EN 14347, is missing in EN 13704 and EN 17126. Thus, an additional control to determine/exclude a sporistatical activity is included.

This information will be taken into account in the revision of EN 17126 and EN 13704 or will be included in the revision of EN 12353 and then referenced in the two standards mentioned.

1 Scope

This document provides additional information and recommendations on the preparation of spores and a test method to determine / exclude sporistatical activity respectively differentiate between sporistatical and sporicidal activity of a product.

2 Normative references

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.

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

4 Information on the determination of the chemical susceptibility of the spore preparation

When testing in accordance with EN 17126 and EN 13704 the following information is taken into account.

Viability is checked and the susceptibility of each spore batch after at least 8 weeks storage at 2 °C to 8°C for *Clostridioides* spores and 4 weeks storage at 2 °C to 8 °C for *Bacillus* spores. Glutardialdehyde is used and peracetic acid at set concentrations. Tests are performed according to the dilution-neutralization method and use hard water instead of an interfering substance. The validation is performed with a suspension adjusted to 1,5 x 10^6 cfu/ml to 5,0 x 10^6 cfu/ml.

Pre-examination studies agreed that at 20 °C ±1 °C:

a) With *Clostridioides difficile* NCTC 13366 without interfering substance:

— 1,0 % (v/v) – 15 min: Glutardialdehyde solution (unbuffered) is achieve a lg reduction of < 1,5 lg.

The pH is within a range of 6,11 ±0,77 [Data from ring trial 2017/2019][1)]

— 6,0 % (v/v) – 15 min: Glutardialdehyde solution (unbuffered) is achieve a lg reduction of ≥ 1,5 lg.

The pH is within a range of 4,48 ±0,31 [Data from ring trial 2017][1)].

— 0,01 % (v/v) – 15 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of < 1,5 lg.

The pH is within a range of 4,92 ±0,28 [Data from ring trial 2017/2019][1)].

— 0,04 % (v/v) – 15 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of ≥ 1,5 lg.

The pH is within a range of 3,94 ±0,11 [Data from ring trial 2017/2019][1)].

1) The. Data based on studies with BIOBAN™ GA 50 Antimicrobial and Lerasept® spezial; the pH values serve as orientation and do not represent a criterion for exclusion, if they are within the range of the relevant pH range.

b) With *Bacillus subtilis* ATCC 6633 without interfering substance:

— 3,0 % (v/v) – 30 min: Glutardialdehyde solution (buffered with $NaHCO_3$) is achieve a lg reduction of < 3 lg.

The pH is equivalent to 7,6 ±0,2.

— 10,0 % (v/v) – 30 min: Glutardialdehyde solution (buffered with $NaHCO_3$) is achieve a lg reduction of ≥ 3 lg.

The pH is equivalent to 7,6 ±0,2.

— 0,001 % (v/v) – 30 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of < 3 lg.

— 0,05 % (v/v) – 30 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of ≥ 3 lg.

c) With *Bacillus cereus* CIP 105151 without interfering substance:

— 0,5 % (v/v) – 15 min: Glutardialdehyde solution (buffered with $NaHCO_3$) is achieve a lg reduction of < 3 lg.

The pH is equivalent to 7,6 ±0,2.

— 3,0 % (v/v) – 15 min: Glutardialdehyde solution (buffered with $NaHCO_3$) is achieve a lg reduction of ≥ 3 lg.

The pH is equivalent to 7,6 ±0,2 .

— 0,05 % (v/v) –30 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of < 3 lg.

— 0,50 % (v/v) – 30 min: Peracetic acid solution (unbuffered) is achieve a lg reduction of ≥ 3 lg.

For the validation, a specific reference product is used. Appropriate substances are glutardialdehyde and peracetic acid. Commercial products of glutardialdehyde are available e.g. BIOBAN™ GA 50 Antimicrobial[2)], glutardialdehyde 50% wt in H_2O from Sigma-Aldrich[2)] and for peracetic acid are available e.g. Lerasept® spezial[2)], peracetic acid 15% pure from AppliChem[2)]. Stored at 4 °C to 8 °C.

The standard test solutions are prepared strictly according to guidance given in Annex A.

For each test of a product solution test in parallel a reference product in low concentration (GA/PAA) which cover the active ingredients of the test product. In the case of chlorine test product, it is recommended to carry along the reference product PAA. The actual active ingredients of peracetic acid are determined by titration the day before (see Annex C) and are considered for the preparation of standard test solutions (see Annex A).

2) The mentioned products are examples of suitable products available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of this product.

5 Information on the determination / exclusion of the sporistatical activity

When testing in accordance with EN 17126 and EN 13704 the following information is taken into account.

In the quantitative suspension test EN 14347 - basic sporicidal activity (phase 1) - a control is included to differentiate between sporistatical and sporicidal activity. This control is missing in the suspension tests of phase 1, step 1 but is relevant to claim sporicidal activity of a product.

The determination of the sporistatical activity is determined strictly according to guidance given in Annex B.

Annex A
(informative)

Guide for preparation of reference test solution

Dilutions of the product are prepared with hard water on a volume/volume basis using volumetric flasks for susceptibility testing of *Clostridioides difficile*, see Table A.1.

Table A.1 —Reference test solution for susceptibility testing of *Clostridioides difficile*

Product	Test concentration %	Concentration of active substance %	Dilution v/v
Glutardialdehyde [50%]	1	1,25	1,25 ml of GA (50%), add hard water up to 50 ml
	6	7,5	7,5 ml of GA (50%), add hard water up to 50 ml
Peracetic acid [5%][b] and H_2O_2 [25%]		1[a]	2 ml of PAA (5 %) add hard water up to 10 ml
	0,01	0,0125	1,25 ml of PAA (1 %)[a] add hard water up to 100 ml
	0,04	0,05	5 ml of PAA (1 %)[a] add hard water up to 100 ml

a 1st step of PAA dilution. Use this dilution of PAA (1 %) to prepare 0,001%, 0,01 %, 0,04%, 0,05% and 0,5 % PAA.

b If peracetic acid is used with an initial concentration of 15% (instead of 5%), the dilution is adjusted accordingly.

For the validation specific reference product are used. Appropriate substances are e.g.: glutardialdehyde or peracetic acid (Annex C).

Dilutions of the product is prepared with hard water on a volume/volume basis using volumetric flasks for susceptibility testing of *B. subtilis* and *B. cereus*, see Table A.2.