

---

**Kemična razkužila in antiseptiki - Informacije o pripravi spor in določanju/izključevanju sporocidnega delovanja**

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

**Ta slovenski standard je istoveten z: CEN/TR 18010:2023**

[SIST-TP CEN/TR 18010:2024](https://standards.slovenski-institut.si/standards/sist-tp-cen-tr-18010-2024)

**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-TP CEN/TR 18010:2024****en**



TECHNICAL REPORT

CEN/TR 18010

RAPPORT TECHNIQUE

TECHNISCHER REPORT

November 2023

ICS 71.100.35

English Version

## Chemical disinfectants and antiseptics - Information on the preparation of spores and determination/exclusion of sporistatistical 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

This Technical Report was approved by CEN on 13 November 2023. It has been drawn up by the Technical Committee CEN/TC 216.

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.

iTeh Standards  
(<https://standards.iteh.ai>)  
Document Preview

[SIST-TP CEN/TR 18010:2024](https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024)

<https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024>



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

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

| <b>Contents</b>  | <b>Page</b> |
|--|-------------|
| European foreword.....   | 3           |
| Introduction .....   | 4           |
| 1 Scope.....   | 5           |
| 2 Normative references.....  | 5           |
| 3 Terms and definitions .....  | 5           |
| 4 Information on the determination of the chemical susceptibility of the spore preparation .....                           | 5           |
| 5 Information on the determination / exclusion of the sporistatcal activity.....   | 7           |
| Annex A (informative) Guide for preparation of reference test solution .....   | 8           |
| Table A.1 —Reference test solution for susceptibility testing of <i>Clostridioides difficile</i> .....                     | 8           |
| Table A.2 —Reference test solution for susceptibility testing of <i>Bacillus subtilis</i> and <i>Bacillus cereus</i> ..... | 9           |
| Annex B (informative) Determination of sporistatcal activity.....  | 10          |
| B.1 General.....   | 10          |
| B.2 Reagents .....   | 10          |
| B.3 Procedure.....   | 10          |
| Annex C (informative) Example for a titration Peracetic acids and hydrogen peroxide .....                                  | 12          |
| C.1 General.....   | 12          |
| C.2 Equipment .....  | 12          |
| C.3 Procedure.....   | 12          |

## **European foreword**

This document (CEN/TR 18010:2023) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[SIST-TP CEN/TR 18010:2024](https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024)

<https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024>

## CEN/TR 18010:2023

### 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 updated 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 problems 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 sporistatcal 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 sporistatcal 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.

# iTeh Standards (<https://standards.iteh.ai>) Document Preview

[SIST-TP CEN/TR 18010:2024](https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024)

<https://standards.iteh.ai/catalog/standards/sist/30813302-2dde-4e43-861f-1055ffbba15a/sist-tp-cen-tr-18010-2024>