SLOVENSKI STANDARD
SIST EN 12353:2001

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Kemična razkužila in antiseptiki - Shranjevanje mikrobioloških sevov za ugotavljanje baktericidnega in fungicidnega delovanja

Chemical disinfectants and antiseptics - Preservation of microbial strains used for the determination of bactericidal and fungicidal activity

Chemische Desinfektionsmittel und Antiseptika - Aufbewahrung von Bakterien- und Pilzstämmen für die Prüfung der bakteriziden und fungiziden Wirkung

Antiseptiques et désinfectants chimiques - Conservation des souches microbiennes utilisées pour la détermination de l'activité bactéricide et fongicide

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71.100.35	Kemikalije za dezinfekcijo v industriji in doma	Chemicals for industrial and domestic disinfection purposes

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

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 216 "Chemical disinfectants and antiseptics", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annex A is normative.

Introduction

Standardized tests for the determination of bactericidal and fungicidal activity necessitate the use of microbial strains whose purity and identity have been verified and whose biological behaviour remains stable. Therefore it is essential to specify the storage requirements. The purpose of this standard is to describe a method for preservation of microbial strains used for the determination of bactericidal and fungicidal activity of chemical disinfectants and antiseptics.

1 Scope

This standard describes a method for keeping microbial strains used for the determination of bactericidal and fungicidal activity of chemical disinfectants and antiseptics.

The standard is only applicable to the strains listed in annex A.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1040, *Chemical disinfectants and antiseptics — Basic bactericidal activity — Test method and requirements (phase 1).*

EN 1275, *Chemical disinfectants and antiseptics — Basic fungicidal activity — Test method and requirements (Phase 1).*

EN 1276, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1).*

EN 1499, *Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2).*

EN 1500, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2).*

EN 1650, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1).*

prEN 1656:1999, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary field - Test method and requirements (phase 2/step 1).*

prEN 1657:1999, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in veterinary field - Test method and requirements (phase 2, step 1).*

prEN 12054:1995, *Chemical disinfectants and antiseptics - Products for hygienic and surgical handrub and handwash - Bactericidal activity - Test method and requirements - (phase 2, step 1).*

ISO 4793, *Laboratory sintered (fritted) filters — Porosity grading, classification and designation.*

3 Terms and definitions

For the purposes of this European Standard, the following definitions apply :

3.1
bactericide
product which kills vegetative bacteria under defined conditions [EN 1040]

NOTE The adjective derived from "bactericide" is "bactericidal".

3.2
bactericidal activity
capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under conditions defined by the relevant standard

3.3
fungicide
product which kills fungi including their spores under defined conditions [EN 1275]

NOTE The adjective derived from "fungicide" is "fungicidal".

3.4
fungicidal activity
capability of a product to produce a reduction in the number of viable vegetative yeast cells and mold spores of relevant organisms under conditions defined by the relevant standard

3.5
conidium
asexual fungal spore, produced exogenously from a hyphal tip

NOTE Conidiospore is a synonym for conidium.

4 Principle

Strains used for chemical antiseptics and disinfectants tests are used for the preparation of a stock culture which is then stored.

5 Materials and reagents

5.1 Microbial strains

Strain identification, origin (culture collection), (see annex A) date of arrival, batch number shall be recorded.

5.2 Culture media and reagents

The final preparation shall be free from substances that are toxic or inhibiting to the microbial cells.

5.2.1 General

The reagents shall be of analytical grade and/or appropriate for microbiological purposes.

NOTE To improve reproducibility, it is recommended that commercially available dehydrated materials are used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed.

5.2.2 Water

It shall be freshly glass distilled and not demineralised water.

Sterilize in the autoclave (see 5.3.1).

NOTE 1 If the water is sterilized during the sterilization of the reagents this is not necessary.

NOTE 2 If distilled water of adequate quality is not available, water for injectable preparations (European Pharmacopoeia) can be used.

5.2.3 Tryptone Soya Broth (TSB)

For resuscitation of freeze-dried samples of bacterial strains.

Tryptone, pancreatic digest of casein	17,0 g
Soya peptone, papaic digest of Soybean meal	3,0 g
NaCl	5,0 g
Water (see 5.2.2)	1 000,0 ml
$K_2H\ PO_4$	2,5 g
Glucose	2,5 g

Sterilize in the autoclave (see 5.3.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C.

5.2.4 Tryptone Soya Agar (TSA)

For maintenance of bacterial strains and performance of viable counts.

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
NaCl	5,0 g
Agar	15,0 g
Water (see 5.2.2)	1 000,0 ml

Sterilize in the autoclave (see 5.3.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 °C.

5.2.5 Malt Extract broth (MEB)

For resuscitation of freeze-dried samples of yeast and mould strains.

Malt extract	20,0 g
Water (see 5.2.2)	1 000,0 ml

Sterilize in the autoclave (see 5.3.1). After sterilization the pH of the medium shall be equivalent to 6,9 ± 0,2 when measured at 20 °C.

5.2.6 Malt Extract agar (MEA)

For maintenance of yeast and mould strains and performance of viable counts.

Malt extract	30,0 g
Soya peptone	3,0 g
Agar	15,0 g
Water (see 5.2.2)	1 000,0 ml