SLOVENSKI STANDARD
SIST EN 13704:2018

01-oktober-2018

Nadomešča:
SIST EN 13704:2002

Kemična razkužila - Kvantitativni suspenzijski preskus za vrednotenje sporocidnega delovanja kemičnih razkužil v živilski in drugih industrijah, gospodinjstvu in javnih ustanovah - Preskusna metoda in zahteve (faza 2, stopnja 1)

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

Chemische Desinfektionsmittel - Quantitativer Suspensionversuch zur Bestimmung der sporiziden Wirkung chemischer Desinfektionsmittel in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

Désinfectants chimiques - Essai quantitatif de suspension pour l'évaluation de l'activité sporicide des désinfectants chimiques utilisés dans le domaine de l'agro-alimentaire, dans l'industrie, dans les domaines domestiques et en collectivité - Méthode d'essai et prescriptions (phase 2, étape 1)

Ta slovenski standard je istoveten z: **EN 13704:2018**

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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 STANDARD

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English Version

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This European Standard was approved by CEN on 16 March 2018.

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

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European foreword

This document (EN 13704:2018) 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of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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.

This document supersedes EN 13704:2002.

It was revised in order to include the spore susceptibility controls, to better detail spore preparation procedures and to harmonize counting and elaboration of the results with the other CEN/TC 216 current standards.

EN 13704:2018 includes the following changes compared to EN 13704:2002:

— inclusion of spore suspension susceptibility controls;

— modification of spore preparation procedures;

— inclusion of spore maturation time;

— harmonization of counting and elaboration of the results with the other CEN/TC 216 current standards;

— deletion of obligatory conditions for contact time and temperature;

— inclusion of minimum and maximum conditions for contact time and temperature;

— inclusion of dirty conditions.

Results obtained with the previous version are not valid.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard describes a suspension test method for establishing whether a chemical disinfectant has or does not have a sporicidal activity in the fields described in Clause 1.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, in suspension, etc.) reflect parameters which are found in practical situations including conditions which can influence the action of disinfectants. Each utilization concentration found from this test corresponds to defined experimental conditions.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types.

However for some applications the recommendations of use of a product can differ and therefore additional test conditions need to be used.

1 Scope

This document specifies a test method (phase 2/step 1) and the minimum requirements for sporicidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation in hard water and that are used in food, industrial, domestic and institutional areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas.

This European Standard applies at least to the following:

a) processing, distribution and retailing of:

   1) food of animal origin:

      — milk and milk products;

      — meat and meat products;

      — fish, seafood, and related products;

      — eggs and egg products;

      — animal feeds;

      — etc.;

   2) food of vegetable origin:

      — beverages;

      — fruits, vegetables and derivatives (including sugar, distillery, etc.);

      — flour, milling and baking;

      — animal feeds;

      — etc.;

b) institutional and domestic areas:

   — catering establishments;

   — public areas;

   — public transports;

   — schools;

   — nurseries;

   — shops;

   — sports rooms;

   — waste containers (bins, etc.);

— hotels;

— dwellings;

— clinically non sensitive areas of hospitals;

— offices;

— etc.;

c) other industrial areas:

— packaging material;

— biotechnology (yeast, proteins, enzymes, etc.);

— pharmaceutical;

— cosmetics and toiletries;

— textiles;

— space industry, computer industry;

— etc.

Using this European Standard, it is not possible to determine the sporicidal activity of undiluted product as some dilution is always produced by adding the inoculum and interfering substance. Products can only be tested at a concentration of 80 % or less.

NOTE The method described is intended to determine the activity of commercial formulations or active substances on spores in the conditions in which they are used.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12353, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

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 Requirements

The product shall demonstrate at least 3 decimal log (lg) reduction, when tested in accordance with Table 1 here below and Clause 5.

Table 1 — Minimum and additional test conditions

Test Conditions for Surface disinfection	
Minimum spectrum of test organisms	*Bacillus subtilis*
Additional sporicidal activity vs anaerobes for specific uses	*Clostridium sporogenes*
Additional sporicidal activity vs aerobes for specific uses	*Bacillus cereus*
Required reduction	≥ 3 lg
Test temperature	according to the manufacturer's recommendation, but between 4 °C and 75 °C
Contact time (in minutes)	according to the manufacturer's recommendation, but between 1 min and 60 min (only contact times of 1, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 min are allowed in this range)
Interfering substance	Clean conditions: 0,3 g/l bovine albumin solution or Dirty conditions: 3,0 g/l bovine albumin solution
Additional interfering substance for dairies	10,0 g / l of reconstituted milk

Other additional strains and additional test conditions may be tested according to product claim.

5 Test method

5.1 Principle

A test suspension of bacterial spores in a solution of interfering substance, simulating clean and/or dirty conditions, is added to a prepared sample of the product under test diluted in hard water (in water for ready-to-use products). The mixture is maintained at specific test temperature ± 1 °C for the specific test contact (time ± 10) s (required test conditions). In case the contact time is 1 min, the tolerance allowed shall be ± 5 s

At this contact time, an aliquot is taken; the sporicidal action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The number of surviving bacterial spores in each sample are determined and the reduction in viable counts is calculated.

5.2 Materials and reagents

5.2.1 Test organisms

The sporicidal activity shall be evaluated by using spores of the following strain :

— *Bacillus subtilis* ATCC 6633 [1)].

If required for specific applications or products, additional strains may be chosen from, for example :

— *Bacillus cereus* CIP 105151;

— *Clostridium sporogenes* ATCC 19404, CIP 79.3 [1)].

NOTE 1 See Annex F for corresponding strain numbers in some other culture collections.

NOTE 2 See Annex C for particular culture and handling conditions for *Clostridium sporogenes*.

NOTE 3 It has been noted that different sources of *Bacillus cereus* strain can lead to different sporulation behaviour, in particular CIP 105151 strain seems to sporulate better.

If additional strains are used, they shall be incubated under optimum growth conditions (temperature, time, atmosphere) and noted in the test report.

If the additional strains selected do not correspond to the specified strains, their suitability for supplying inocula of sufficient concentration shall be verified. If the additional strains tested are not classified at a reference centre their identification characteristics shall be stated. In addition, they shall be held by the testing laboratory or national culture under a reference for 5 years.

5.2.2 Culture media and reagents

5.2.2.1 General

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

5.2.2.2 Water

The water shall be free from substances that are toxic or inhibiting to the bacterial spores or to the bacteria. It shall be freshly glass distilled water and not demineralized water.

Sterilize in the autoclave (5.3.2.1). Sterilization is not necessary if the water is used e.g. for preparation of culture media and subsequently sterilized. If distilled water of adequate quality is not available, water for injectable preparation can be used.

See 5.2.2.6 for preparation of hard water.

5.2.2.3 Tryptone Soja Agar (TSA)

For counting of viable *Bacillus* spores :

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papaic digest of Soybean meal	5,0 g
Sodium Chloride (NaCl)	5,0 g

1) ATCC 6633 and ATCC 19404 are the collection numbers of strains supplied by the American Type Culture Collections. CIP 79.3 is the collection number of spores supplied by the Collection de l'Institut Pasteur. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named. Corresponding strains supplied by other culture collections may be used if they can be shown to lead to the same results.

Agar	15,0 g
Water (see 5.2.2.2)	1 000,0 ml

Sterilize in the autoclave (5.3.2.1). After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 measured at (20 ± 1) °C

5.2.2.4 Neutralizer

The neutralizer shall be validated for the product under test in accordance with Annex D. The neutralizer shall be sterile.

NOTE Information on neutralizers that have been found to be suitable for some categories of products is given in Annex D.

5.2.2.5 Rinsing liquid (for membrane filtration)

The liquid shall be sterile, compatible with the filter membrane and capable of filtration through the filter membrane under the test conditions described in Annex B.

NOTE Information on rinsing liquids that have been found to be suitable for some categories of products is given in Annex D.

5.2.2.6 Hard water for dilution of products

For the preparation of 1 l of hard water, the procedure is as follows:

— prepare solution A: dissolve 19,84 g magnesium chloride ($MgCl_2$) and 46,24 g calcium chloride ($CaCl_2$) in water (5.2.2.2) and dilute to 1000 ml. Sterilize by membrane filtration (5.3.2.7) or in the autoclave (5.3.2.1 a)). Autoclaving – if used - may cause a loss of liquid. In this case make up to 1000 ml with water (5.2.2.2) under aseptic conditions. Store the solution in the refrigerator at 5 °C ± 3 °C (according 5.3.2.15) for no longer than four weeks;

— prepare solution B: dissolve 35,02 g sodium bicarbonate ($NaHCO_3$) in water (5.2.2.2) and dilute to 1000 ml. Sterilize by membrane filtration (5.3.2.7). Store the solution in the refrigerator at 5 °C ± 3 °C (according 5.3.2.15) for no longer than one week;

— place 600 ml to 700 ml of water (5.2.2.2) in a 1000 ml volumetric flask (5.3.2.12) and add 6,0 ml (5.3.2.9) of solution A, then 8,0 ml of solution B. Mix and dilute to 1000 ml with water (5.2.2.2). The pH of the hard water shall be (7,0 ± 0,2), when measured at (20 ± 1) °C (5.3.2.4). If necessary, adjust the pH by using a solution of approximately 40 g/l (about 1 mol/l) of sodium hydroxide (NaOH) or approximately 36,5 g/l (about 1 mol/l) of hydrochloric acid (HCl).

The hard water shall be freshly prepared under aseptic conditions and used within 12 h.

NOTE When preparing the product test solutions (5.4.2), the addition of the product to the hard water produces a different final water hardness in each test tube. In any case the final hardness expressed as calcium carbonate ($CaCO_3$) is in the test tube lower than 375 mg/l.

5.2.2.7 Interfering substance

5.2.2.7.1 General

The interfering substance shall be sterile and prepared at 10 times its final concentration in the test.

5.2.2.7.2 Clean conditions

Bovine albumin solution for the test conditions shall be prepared as follows:

— dissolve 0,30 g of bovine albumin fraction V (suitable for microbiological purposes) in 100 ml of water (see 5.2.2.2) ;

— sterilize by membrane filtration (5.3.2.7).

The final concentration of the bovine albumin in the test procedure (5.5.2) is 0,3 g/l.

5.2.2.7.3 Dirty conditions

Dissolve 3,00 g of bovine albumin fraction V (suitable for microbiological purposes) in 100 ml of water (5.2.2.2).

Sterilize by membrane filtration (5.3.2.7).

The final concentration of bovine albumin in the test procedure (5.5.2) shall be 3,0 g/l.

5.2.2.7.4 Additional interfering substance for dairies

Skimmed milk, guaranteed free of antibiotics and additives and reconstituted at a rate of 100 g powder per litre of water (5.2.2.2), shall be prepared as follows:

— prepare a solution of 100 g milk-powder in 1 000 ml water (5.2.2.2). Heat for 30 min at (105 ± 3) °C [or 5 min at (121 ± 3) °C].

The final concentration of reconstituted milk in the test procedure (5.5.1,c)) is 10,0 g/l of reconstituted milk.

5.3 Apparatus and glassware

5.3.1 General

Sterilize all glassware and parts of the apparatus that will come into contact with the culture media and reagents or the sample, except those which are supplied sterile, by one of the following methods :

a) in the autoclave (see 5.3.2.1);

b) in the dry heat sterilizer (see 5.3.2.1).

5.3.2 Usual microbiological laboratory equipment[2)] and, in particular, the following

5.3.2.1 Apparatus for sterilization

a) for moist heat sterilization, an autoclave capable of being maintained at (121^{+3}_{0}) °C for a minimum holding time of 15 min ;

b) for dry heat sterilization, a hot air oven capable of being maintained at 180 °C for a minimum holding time of 30 min, at 170 °C for a minimum holding time of 1 h, or at 160 °C a minimum holding time of 2 h.

2) Disposable equipment is an acceptable alternative to reusable glassware.