SLOVENSKI STANDARD

SIST EN 13697:2002

01-september-2002

Kemična razkužila in antiseptiki - Kvantitativni preskus na neporoznih površinah za ocenjevanje baktericidnega in/ali fungicidnega delovanja kemičnih razkužil v živilski in drugih industrijah, gospodinjstvu in javnih ustanovah - Preskusna metoda in zahteve brez mehanskega delovanja (faza 2/stopnja 2)

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2/step2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Oberflächen-Versuch zur Bestimmung der bakteriziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren ohne mechanische Behandlung und Anforderungen (Phase 2/Stufe 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface non-poreuse pour l'évaluation de l'activité bactéricide et/ou fongicide des désinfectants chimiques utilisés dans le domaine de l'agro-alimentaire, dans l'industrie, dans les domaines domestiques et en collectivité - Méthode d'essai sans action mécanique et prescriptions (phase 2/étape 2)

Ta slovenski standard je istoveten z: **EN 13697:2001**

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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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This European Standard was approved by CEN on 25 July 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 February 2002, and conflicting national standards shall be withdrawn at the latest by February 2002.

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information.

Annex A is normative.

Annex B, C, D and E are informative.

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.

Introduction

This European Standard describes a surface test method for establishing whether a product proposed as a disinfectant in the fields described in clause 1 has or does not have bactericidal and/or fungicidal activity on non-porous surfaces.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, organisms on surfaces ...) reflect parameters which are found in practical situations including conditions which may influence the action of disinfectants. Each use 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 European Standard specifies a test method (phase 2/step 2) and the minimum requirements for bactericidal and/or fungicidal activity of chemical disinfectants 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.

The scope of 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 products ;

— eggs and egg products ;

— animal feeds ;

— etc.

2) Food of vegetable origin :

— beverages ;

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

— flour, milling and backing ;

— animal feeds ;

— etc.

b) Institutional and domestic areas :

— catering establishments ;

— public areas ;

— public transports ;

— schools ;

— nurseries ;

— shops ;

— sports rooms ;

— waste container (bins) ;

— hotels ;

— dwellings ;

— clinically non sensitive areas of hospitals ;

- offices ;
- etc.

c) Other industrial areas :

- packaging material ;
- biotechnology (yeast, proteins, enzymes...) ;
- pharmaceutical ;
- cosmetics and toiletries ;
- textiles ;
- space industry, computer industry ;
- etc.

Using this European Standard, it is possible to determine the bactericidal or fungicidal activity of the undiluted product. As three concentrations have to be tested, in the active to non active range, dilution of the product is required and, therefore, the product shall form a homogeneous stable preparation in hard water.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances on bacteria and/or fungi in the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2/step 2 test (see annex E).

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 (including amendments).

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 10088-1, *Stainless steels – Part 1: List of stainless steel.*

EN 10088-2, *Stainless steels. Technical delivery conditions for sheet/plate and strip for general purposes.*

EN 12353, *Chemical disinfectants and antiseptics - Preservation of microbial strains used for the determination of bactericidal and fungicidal activity.*

3 Terms and definitions

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

3.1
product (for chemical disinfection and/or antisepsis)
chemical agent or formulation used as a chemical disinfectant [EN 1040]

3.2
bactericide
product which kills vegetative bacteria under defined conditions [EN 1040]

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

3.3
bactericidal activity on surfaces
capability of a product to produce at least a 10^4 reduction in the number of viable bacterial cells belonging to reference strains of *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae* within 5 min at 20 °C under conditions defined by this European Standard

3.4
fungicide
product which kills fungi including their spores under defined conditions [EN 1275]

3.5
fungicidal activity on surfaces
capability of a product to produce at least a 10^3 reduction in number of viable fungi belonging to reference strains of *Candida albicans and Aspergillus niger* within 15 min at 20 °C under conditions defined by this European Standard

3.6
clean conditions
conditions representative of surfaces which have received a satisfactory cleaning programme and/or are known to contain minimal levels of organic and/or inorganic materials [EN 1276]

3.7
dirty conditions
conditions representative or surfaces which are known to or may contain, organic and/or inorganic materials [EN 1276]

4 Requirements

4.1 Requirements for bactericidal activity on surfaces

The product, when diluted in hard water and tested in accordance with clause 5, under simulated clean conditions (0,3 g/l bovine albumin and 1g/l tryptone, see 3.6) or dirty conditions (3 g/l bovine albumin and 1g/l tryptone, see 3.7) according to its practical applications and under the required test conditions shall demonstrate at least a 10^4 reduction in viable bacterial counts

For a claim of bactericidal activity on surfaces for general purposes, the bactericidal activity shall be evaluated using the following four strains : *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterococcus hirae* and *Escherichia coli* at a temperature between 18°C ± 1°C and 25°C ± 1°C and a contact time of 5 min.

The determined bactericidal concentration of the test product is suggested as being suitable for practical situations of use.

Where appropriate (specific purposes), additional specific bactericidal activity shall be determined under other conditions of time, temperature, additional strains and interfering substances (see 5.2.1 and 5.2.2.8) in accordance with 5.5.1 in order to take into account intended specific use conditions.

NOTE For these additional conditions the concentration defined as a result can be lower than the one obtained under the initial conditions, at a temperature between 18 °C ± 1 °C and 25 °C ± 1 °C, 5 min, 4 selected reference strains.

Products under test shall at least possess a bactericidal activity as specified in EN 1040.

4.2 Requirements for fungicidal activity on surfaces

The product, when diluted in hard water and tested in accordance with clause 5, under simulated clean conditions (0,3 g/l bovine albumin and 1g/l tryptone, see 3.6) or dirty conditions (3 g/l bovine albumin, see 3.7) according to its practical applications and under the required test conditions shall demonstrate at least a 10^3 reduction in viable fungal counts.

For a claim of fungicidal activity on surfaces for general purposes, the fungicidal activity shall be evaluated using the following two strains : *Candida albicans*, and *Aspergillus niger* at a temperature between 18 °C ± 1 °C and 25 °C ± 1 °C and a contact time of 15 min.

Where appropriate (specific purposes), additional specific fungicidal activity shall be determined under other conditions of time, temperature, additional strains and interfering substances (see 5.2.1 and 5.2.2.8) in accordance with 5.5.1 in order to take into account intended specific use conditions.

NOTE For these additional conditions the concentration defined as a result can be lower than the one obtained under the initial conditions at a temperature between 18 °C ± 1 °C and 25 °C ± 1 °C, 15 min, 2 selected reference strains.

Products under test shall at least possess a fungicidal activity as specified in EN 1275.

4.3 Requirements for bactericidal and fungicidal activity on surfaces

The product, when diluted in hard water and tested in accordance with clause 5, under simulated clean conditions (0,3 g/l bovine albumin and 1g/l tryptone, see 3.6) or dirty conditions (3 g/l bovine albumin, see 3.7) according to its practical applications and under the required test conditions shall demonstrate at least a 10^4 reduction in viable bacterial counts (*Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterococcus hirae*, *Escherichia coli*) and a 10^3 reduction in viable fungal counts (*Candida albicans* and *Aspergillus niger*).

The determined bactericidal and/or fungicidal concentration of the tested product is suggested as being suitable for general, practical situations of use (see 5.6.3).

Where appropriate, additional specific bactericidal and/or fungicidal activity shall be determined under other conditions of time, temperature, additional strains and interfering substances (see 5.2.1 and 5.5.1) in accordance with 5.5.1 in order to take into account intended specific use conditions.

NOTE For these additional conditions the concentration defined as a result can be lower than the one obtained under the initial conditions, at a temperature between 18 °C ± 1 °C and 25 °C ± 1 °C, 5 min and/or 15 min, with selected reference strains.

This European Standard is applicable only to disinfectants and antiseptics, complying with EN 1040 (for bactericidal activity) and/or EN 1275 (for fungicidal activity).

5 Test method

5.1 Principle

A test suspension of bacteria or fungi in a solution of interfering substances is inoculated onto a test stainless steel surface and dried. A prepared sample of the product under test is applied in a manner which covers the dried film. The surface is maintained at a specified temperature for a defined period of time. The surface is transferred to a previously validated neutralisation medium so that the action of the disinfectant is immediately neutralised. The number of surviving organisms which can be recovered from the surface is determined quantitatively.

The number of bacteria or fungi on a surface treated with hard water in place of the disinfectant is also determined and the reduction in viable counts attributed to the product is calculated by difference.

5.2 Materials and reagents

5.2.1 Test organisms

The bactericidal activity shall be evaluated using the following four strains :

— *Pseudomonas aeruginosa* ATCC 15 442 [1)] ;

1) ATCC 15 442, ATCC 6 538, ATCC 10 541, ATCC 10 536, ATCC 10 231, ATCC 16 404 and ATCC 13311 are the collection numbers of strains supplied by the American Type Culture Collections. DSM 6 235, DSM 6 234, DSM 1333 and DSM 70487 are the collection numbers of strains supplied by the DSMZ (Deutsche Sammlung von Mikroorganismen und Zellkulturen). This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named. Equivalent products can be used if they can be shown to lead to the same results.

— *Staphylococcus aureus* ATCC 6 538 ;

— *Enterococcus hirae* ATCC 10 541 ;

— *Escherichia coli* ATCC 10 536.

The fungicidal activity shall be evaluated using the following two strains :

— *Candida albicans* ATCC 10 231 ;

— *Aspergillus niger* ATCC 16 404.

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

— *Salmonella typhimurium* ATCC 13 311 ;

— *Lactobacillus brevis* DSM 6 235 ;

— *Enterobacter cloacae* DSM 6 234 ;

— *Saccharomyces cerevisiae* (for breweries) or ATCC 9 763 or DSM 1 333 ;

— *Saccharomyces cerevisiae* var. *diastaticus* (for breweries) DSM 70 487.

NOTE See annex D for corresponding strain numbers in some other culture collections.

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.

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

5.2.2.2 Water

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

Sterilise in the autoclave (see 5.3.2.1).

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

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

5.2.2.3 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 5.2.2.2)	1 000,0 ml

Sterilise in the autoclave (see 5.3.2.1). After sterilisation the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at 20 C.

5.2.2.4 Malt extract agar (MEA)

For maintenance of fungal strains, sporulation and performance of viable counts.

Malt extract (technical grade)	30,0 g
Soya peptone	3,0 g
Agar	15,0 g
Water (see 5.2.2.2)	1 000,0 ml

Sterilise in the autoclave (see 5.3.2.1). After sterilisation the pH of the medium shall be equivalent to 5,6 ± 0,2 when measured at 20 °C.

5.2.2.5 Diluent

Tryptone sodium chloride solution :

Tryptone, pancreatic digest of casein	1,0 g
NaCl	8,5 g
Water (see 5.2.2.2)	1 000,0 ml

Sterilise in the autoclave (see 5.3.2.1). After sterilisation the pH shall be equivalent to 7,0 ± 0,2 when measured at 20 °C.

5.2.2.6 Neutraliser

The neutraliser shall be validated for the product under test in accordance with annex A. The neutraliser shall be sterile.

NOTE Information on neutralisers that have been found to be suitable for some categories of products is given in annex B.

5.2.2.7 Hard water for dilution of the products

Hard water for dilution of products shall be prepared as follows :

— solution A : Dissolve 19,84 g anhydrous $MgCl_2$ and 46,24 g anhydrous $CaCl_2$ in water (see 5.2.2.2) and dilute to 1 000 ml ;