STN	Chemické dezinfekčné a antiseptické prípravky. Kvantitatívna nepórovitá povrchová skúška na vyhodnotenie baktericídnej a/alebo fungicídnej aktivity chemických dezinfekčných prípravkov	STN EN 13697
	používaných v potravinárstve, priemysle, v domácnostiach a inštitúciách. Skúšobná metóda a požiadavky bez mechanického pôsobenia (fáza 2, krok 1).	85 7021

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

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/15

Obsahuje: EN 13697:2015

Oznámením tejto normy sa ruší STN EN 13697 (85 7021) z apríla 2003

121240

Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2015 Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

EUROPEAN STANDARD NORME EUROPÉENNE

EN 13697

EUROPÄISCHE NORM

April 2015

ICS 11.080.20; 71.100.35

Supersedes EN 13697:2001

English Version

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

This European Standard was approved by CEN on 20 January 2015.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

© 2015 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN 13697:2015 E

Contents

Forewo	ord	3
Introduction		4
1	Scope	5
2	Normative references	6
3	Terms and definitions	6
4	Requirements	7
5	Test methods	
5.1	Principle	
5.2 5.2.1	Materials and reagents Test organisms	
5.2.1	Culture media and reagents	
5.2.3	Test surface	
5.3	Apparatus and glassware	
5.4	Preparation of test organism suspensions and product test solutions	14
5.4.1	Test organism suspensions	
5.4.2	Product test solutions	
5.5	Procedure	
5.5.1 5.5.2	Choice of experimental conditions Test procedure	
5.5.2 5.5.3	Counting of the test mixtures	
5.6	Calculation and expression of results	
5.6.1	Elaboration of data: counting of weighed average values	
5.6.2	Verification of methodology	
5.6.3	Expression of results	23
5.6.4	Conclusion	
5.7	Test report	24
Annex	A (informative) Corresponding referenced strains	26
Annex	B (informative) Neutralizers	28
Annex	C (informative) Expression of results with the dilution-neutralization method	30
Annex	D (informative) Bactericidal activity in surfaces in general use conditions (for clean conditions)	32
Annex	E (informative) Precision of the test result	33
Bibliog	raphy	34

Foreword

This document (EN 13697:2015) 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 October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.

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

This document supersedes EN 13697:2001.

The changes between this edition and EN 13697:2001 are the following:

- interfering substance has been changed from 0,03 % bovine albumin to 0,85 % skimmed milk (see Clause 4, Table 1) for *Pseudomonas aeruginosa* under clean conditions only;
- A. brasiliensis (ex A. niger) spore preparation has been updated in order to harmonize this step with the QST fungicidal test method amendment issued in 2012 (see 5.4.1.3 b));
- Calculations of the weighed means and of the results have been modified in order to be harmonized with new CEN TC 216 standards (see 5.4.1.5, 5.5.2, 5.5.3 and 5.6);
- Other paragraphs have been harmonized to new CEN TC 216 standards (e.g. preparation of hard water, 5.2.2.7).

Results obtained from the previous standard for *Aspergillus niger* need to be repeated to take into account the new spore morphology requirement and the change in interfering substance.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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 or yeasticidal activity on non-porous surfaces.

This European Standard has been revised in order to modify the interfering substance under "clean conditions" adopted for *P. aeruginosa*; in order to modify the calculation of N, NC, NT, Nc, Na and consequently the final results and to harmonize the standard with the other recent CEN TC 216 standards.

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 or yeasticidal activity of chemical disinfectants that form a homogeneous physically stable preparation in hard water or – in the case of ready-to-use products – with water 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:
 - i) milk and milk products;
 - ii) meat and meat products;
 - iii) fish, seafood and products;
 - iv) eggs and egg products;
 - v) animal feeds;
 - vi) etc.
 - 2) Food of vegetable origin:
 - i) beverages;
 - ii) fruits, vegetables and derivatives (including sugar distillery);
 - iii) flour, milling and backing;
 - iv) animal feeds;
 - v) etc.
- b) Institutional and domestic areas:
 - 1) catering establishments;
 - 2) public areas;
 - 3) public transports;
 - 4) schools;
 - 5) nurseries;
 - 6) shops;
 - 7) sports rooms;
 - 8) waste container (bins);

- 9) hotels;
- 10) dwellings;
- 11) clinically non sensitive areas of hospitals;
- 12) offices;
- 13) etc.
- c) Other industrial areas:
 - 1) packaging material;
 - 2) biotechnology (yeast, proteins, enzymes...);
 - 3) pharmaceutical;
 - 4) cosmetics and toiletries;
 - 5) textiles;
 - 6) space industry, computer industry;
 - 7) etc.

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

EN 14885 specifies in detail the relationship of the various tests to one another and to use recommendations.

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 cannot be used to evaluate the activity of products against mycobacteria.

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

ISO 4793, Laboratory sintered (fritted) filters - Porosity grading, classification and designation

koniec náhľadu – text ďalej pokračuje v platenej verzii STN