

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)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 13697:2015+A1:2019 sisaldab Euroopa standardi EN 13697:2015+A1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 13697:2015+A1:2019 consists of the English text of the European standard EN 13697:2015+A1:2019.
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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 zur Bestimmung der bakteriziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel auf nicht porösen Oberflächen 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 and includes Amendment 1 approved by CEN on 10 June 2019.

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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.

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European foreword

This document (EN 13697:2015+A1:2019) 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 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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 includes Amendment 1 approved by CEN on 10 June 2019.

This document supersedes A1 EN 13697:2015 A1.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

A1 The changes between EN 13697:2015+A1:2019 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);
- deletion of obligatory and additional conditions (see Table 1 and 5.5.1);
- update of Bovine albumin and skimmed solutions preparations (see 5.2.2.8.2);
- add of instruction for using vacuum desiccator;
- update on bacteria working culture preparation (see 5.4.1.2) and counting of bacterial and fungal test suspensions (see 5.4.1.4);
- clarification to the determination of microbicidal concentrations by updating 5.5.2.1 b) and adding pictures of carriers;
- updates on dilution preparation for fungal and bacterial strains (see 5.5.2.2, 5.5.2.3, 5.5.2.4) and counting of test mixtures (5.5.3).

Data from EN 13697:2015 are still valid with the exception of:

- *Pseudomonas aeruginosa* and *Candida albicans* under clean conditions. A1

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, Republic of North 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.

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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 baking;
 - 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*