

Nadomešča:**SIST EN 13697:2015+A1:2019**

Kemična razkužila in antiseptiki - Kvantitativni preskus na neporoznih površinah brez mehanskega delovanja za vrednotenje baktericidnega in/ali fungicidnega delovanja ter delovanja kemičnih razkužil na kvasovke 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 yeasticidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas without mechanical action - Test method and requirements without mechanical action (phase 2, step 2)

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

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface non poreuse pour l'évaluation de l'activité bactéricide, levuricide et/ou fongicide des désinfectants chimiques utilisés sans action mécanique 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 13697:2023

EUROPEAN STANDARD

EN 13697

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2023

ICS 71.100.35

Supersedes EN 13697:2015+A1:2019

English Version

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas without mechanical action - 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, levuricide et/ou fongicide des désinfectants chimiques utilisés sans action mécanique 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 levuroziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel auf nicht porösen Oberflächen in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen ohne mechanische Behandlung - Prüfverfahren und Anforderungen ohne mechanische Behandlung (Phase 2, Stufe 2)

This European Standard was approved by CEN on 4 September 2023.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3
Introduction	5
1 Scope.....	6
2 Normative references.....	7
3 Terms and definitions	8
4 Requirements	8
5 Test methods	10
5.1 Principle	10
5.2 Materials and reagents.....	10
5.2.1 Test organisms.....	10
5.2.2 Culture media and reagents	11
5.2.3 Test surface	14
5.3 Apparatus and glassware	14
5.4 Preparation of test organism suspensions and product test solutions.....	15
5.4.1 Test organism suspensions	15
5.4.2 Product test solutions.....	19
5.5 Procedure.....	19
5.5.1 Choice of experimental conditions	19
5.5.2 Test procedure	20
5.5.3 Quantifying of the test mixtures	24
5.6 Calculation and expression of results.....	25
5.6.1 Elaboration of data: counting of weighed average values.....	25
5.6.2 Verification of methodology.....	26
5.6.3 Expression of results.....	26
5.6.4 Conclusion.....	26
5.7 Test report.....	27
Annex A (informative) Corresponding referenced strains	30
Annex B (informative) Neutralizers	32
Annex C (informative) Expression of results with the dilution-neutralization method.....	34
Annex D (informative) Bactericidal activity in surfaces in general use conditions (for clean conditions).....	36
Annex E (informative) Precision of the test result.....	38
Annex F (informative) Alternative drying end point.....	39
Bibliography	41

European foreword

This document (EN 13697:2023) 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 May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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 13697:2015+A1:2019.

The main changes compared to the previous version EN 13697:2015+A1:2019 amending edition EN 13697:2015 are listed below:

- the inoculum under clean conditions for *Pseudomonas aeruginosa* and *Candida albicans* has been reduced to the previous level as in EN 13697:2015;
- a more exact monitoring of the drying process has been included as Annex F (informative) in order to support achieving sufficient levels of surviving cells for valid results;
- inclusion of yeasticidal activity in the title of the document;
- clarification that 1 % reconstituted milk can be used as sole soiling in dairy industry (no need to test BSA);
- the designation of variables *N_d*, *N_c*, *N_C* and *N_T* have been renamed to *N_a*, *A*, *B* and *C* for harmonization with other CEN TC 216 standards;
- clarification of the counting procedure in 5.5.3;
- correction of the Formulae (2) and (3) in 5.5.3;
- correction of the calculation error for counts 0/0, resulting now in “lg = 0,7”;
- *Listeria monocytogenes* has been included as additional test organism;
- several editorial corrections and clarifications have been made.

The following changes in version EN 13697:2015+A1:2019 amending edition EN 13697:2015 were maintained:

- deletion of obligatory and additional conditions (see Table 1 and 5.5.1);
- update of Bovine albumin and skimmed milk solutions preparations (see 5.2.2.8.2 and 5.2.2.8.3 respectively);
- add of instruction for using vacuum desiccator;
- clarification to the determination of microbicidal concentrations by updating 5.5.2.1 b) and adding pictures of carriers.

EN 13697:2023 (E)

Data obtained from EN 13697:2015 and from EN 13697:2015+A1:2019 are still valid. Data obtained from EN 13697:2001 are still valid with the exception of *Aspergillus brasiliensis* (due to modified spore preparation).

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[SIST EN 13697:2023](https://standards.iteh.ai/catalog/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023)

<https://standards.iteh.ai/catalog/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023>

Introduction

This document 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 yeasticidal and/or fungicidal activity on non-porous surfaces.

This document has been revised in order to modify the test parameters under “clean conditions” adopted for *P. aeruginosa* and *C. albicans*; in order to harmonize the designation of test variables *N, B, C, A, Na* with the other recent CEN TC 216 standards and to clarify and/or correct details in colony counting and calculation.

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 can influence the action of disinfectants. Each use concentration found from this test corresponds to specified 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.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[SIST EN 13697:2023](https://standards.iteh.ai/catalog/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023)

<https://standards.iteh.ai/catalog/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023>

EN 13697:2023 (E)**1 Scope**

This document specifies a test method (phase 2/step 2) and the minimum requirements for bactericidal and yeasticidal and/or fungicidal 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.

This document applies to products that are used for disinfecting non-porous surfaces without mechanical action.

This document is applicable 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 distilleries and sugar refineries);

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;

iTeh Standards
(<https://standards.itih.ai>)
Document Preview

[SIST EN 13697:2023](https://standards.itih.ai/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023)

<https://standards.itih.ai/standards/sist/39e94aa6-0a05-42e5-acd0-db717493fd84/sist-en-13697-2023>

- 8) waste containers (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.

This document does not apply when the product is applied via an automatic airborne disinfection method; in such cases, see EN 17272.

Using this document, it is possible to determine the bactericidal and yeasticidal and/or fungicidal activity of the undiluted product. As three concentrations are tested, in the active to non-active range, dilution of the product is needed 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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*

EN 13697:2023 (E)

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online Browsing Platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Requirements

The product shall demonstrate at least a 4 decimal log (lg) reduction for bacteria and at least a 3 decimal log (lg) reduction for fungi, when tested in accordance with Table 1 and 5.5.1.

Table 1 — Experimental conditions

Test conditions	Bactericidal activity on non-porous surfaces without mechanical action	Yeasticidal activity on non-porous surfaces without mechanical action	Fungicidal activity on non-porous surfaces without mechanical action
Test organisms (see 5.2.1) minimum spectrum of test organisms	<i>Enterococcus hirae</i> <i>Escherichia coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i>	<i>Candida albicans</i>	<i>Candida albicans</i> <i>Aspergillus brasiliensis</i>
Test organisms additional (examples)	<i>Salmonella typhimurium</i> <i>Lactobacillus brevis</i> <i>Enterobacter cloacae</i>	<i>Saccharomyces cerevisiae</i> (for breweries) <i>Saccharomyces cerevisiae</i> var. <i>diastaticus</i> (for breweries)	any relevant test organism
Test temperature	In a range from $(4 \pm 1)^\circ\text{C}$ to $(40 \pm 1)^\circ\text{C}$ For tests performed at room temperature, the range shall be between 18°C and 25°C	In a range from $(4 \pm 1)^\circ\text{C}$ to $(40 \pm 1)^\circ\text{C}$ For tests performed at room temperature, the range shall be between 18°C and 25°C	In a range from $(4 \pm 1)^\circ\text{C}$ to $(40 \pm 1)^\circ\text{C}$ For tests performed at room temperature, the range shall be between 18°C and 25°C

Test conditions	Bactericidal activity on non-porous surfaces without mechanical action	Yeasticidal activity on non-porous surfaces without mechanical action	Fungicidal activity on non-porous surfaces without mechanical action
Contact time	in a range from 1 min to 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)	in a range from 1 min to 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)	in a range from 1 min to 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)
Interfering substance clean conditions	0,3 g/l bovine albumin for <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i> , <i>Escherichia coli</i> and <i>Pseudomonas aeruginosa</i>	0,3 g/l bovine albumin for <i>C. albicans</i>	0,3 g/l bovine albumin for <i>C. albicans</i> and <i>A. brasiliensis</i>
Interfering substance dirty conditions	3,0 g/l bovine albumin for <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i> , <i>Pseudomonas aeruginosa</i> and <i>Escherichia coli</i>	3,0 g/l bovine albumin for <i>C. albicans</i>	3,0 g/l bovine albumin for <i>C. albicans</i> and <i>A. brasiliensis</i>
Interfering substance in dairy industry	1,0 % reconstituted milk (= 1,0 g/l milk powder)	1,0 % reconstituted milk (= 1,0 g/l milk powder)	1,0 % reconstituted milk (= 1,0 g/l milk powder)
Interfering substance additional	any relevant substance	any relevant substance	any relevant substance
Log reduction from a water control (decimal lg)	≥ 4 lg	≥ 3 lg	≥ 3 lg

The referenced test conditions (General purposes) are by no means intended as requirements for the use of a product, nor as requirements for the evaluation and acceptance of products by regulatory authorities.

The application time for the product is specified by the manufacturer.

If specific applications are considered, the bactericidal/yeasticidal/fungicidal activity shall be determined additionally under relevant conditions concerning application time, temperature, strains and interfering substances.

5 Test methods

5.1 Principle

An inoculum test suspension consisting 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 specified period of time. The surface is transferred to a previously validated neutralization medium so that the action of the disinfectant is immediately neutralized. 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® 15442™¹;
- *Staphylococcus aureus* ATCC® 6538™;
- *Enterococcus hirae* ATCC® 10541™;
- *Escherichia coli* ATCC® 10536™.

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

- *Candida albicans* ATCC® 10231™;
- *Aspergillus brasiliensis* (*ex A. niger*) ATCC® 16404™.

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

- *Salmonella typhimurium* ATCC® 13311™;
- *Lactobacillus brevis* DSM 6235;
- *Enterobacter cloacae* DSM 6234;
- *Listeria monocytogenes* ATCC® 15313™ or ATCC® 19117™
- *Saccharomyces cerevisiae* (for breweries) or ATCC® 9763™ or DSM 1333;
- *Saccharomyces cerevisiae* var. *diastaticus* (for breweries) DSM 70487.

NOTE See Annex A 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.

¹ ATCC® 15442™, ATCC® 6538™, ATCC® 10541™, ATCC® 10536™, ATCC® 10231™, ATCC® 16404™, ATCC® 13311™, ATCC® 15313™, ATCC® 19117™ and ATCC® 9763™ are the trademarks of products supplied by the American Type Culture Collections. This information is given for the convenience of users of this document 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.