

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 1650:2019 sisaldab Euroopa standardi EN 1650:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 1650:2019 consists of the English text of the European standard EN 1650:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 14.08.2019.	Date of Availability of the European standard is 14.08.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 71.100.35

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

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

Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l'évaluation de l'activité fongicide ou levuricide des antiseptiques et 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)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der fungiziden oder levuroziden Wirkung chemischer Desinfektionsmittel und Antiseptika in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 10 June 2019.

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, Turkey 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	4
Introduction	5
1 Scope	6
2 Normative references	7
3 Terms and definitions	7
4 Requirements	7
5 Test method	9
5.1 Principle	9
5.2 Materials and reagents	10
5.2.1 Test organisms	10
5.2.2 Culture media and reagents	10
5.3 Apparatus and glassware	13
5.4 Preparation of test organism suspensions and product test solutions	14
5.4.1 Test organism suspensions (test and validation suspension)	14
5.4.2 Product test solutions	18
5.5 Procedure for assessing the fungicidal or yeasticidal activity of the product	19
5.5.1 General	19
5.5.2 Dilution-neutralization method	20
5.5.3 Membrane filtration method	22
5.6 Experimental data and calculation	24
5.6.1 Explanation of terms and abbreviations	24
5.6.2 Calculation	25
5.7 Verification of methodology	28
5.7.1 General	28
5.7.2 Control of weighted mean counts	28
5.7.3 Basic limits	28
5.7.4 Microscopic observation	28
5.8 Expression of results and precision	29
5.8.1 Reduction	29
5.8.2 Control of active and non-active product test solution (5.4.2)	29
5.8.3 Limiting test organism and fungicidal/yeasticidal concentration	29
5.8.4 Precision, replicates	29
5.9 Interpretation of results - conclusion	30
5.9.1 General	30
5.9.2 Fungicidal activity for general purposes	30
5.9.3 Yeasticidal activity for general purposes	30
5.9.4 Yeasticidal activity for hand hygiene	30
5.10 Test report	30
Annex A (informative) Referenced strains in national collections	32
Annex B (informative) Examples of neutralizers of the residual antimicrobial activity of chemical disinfectants and antiseptics and rinsing liquids	33
Annex C (informative) Graphical representations of dilution-neutralization method and membrane filtration method	35

Annex D (informative) Example of a typical test report..... 39
Annex E (informative) Precision of the test result 44
Bibliography 47

This document is a preview generated by EVS

European foreword

This document (EN 1650:2019) 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 February 2020 and conflicting national standards shall be withdrawn at the latest by February 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 supersedes EN 1650:2008+A1:2013.

Data obtained by using the latest version of EN 1650:2008+A1:2013 are still valid.

The main changes in relation to EN 1650:2008+A1:2013 are:

- inclusion of hand hygiene;
- handrub and handwash test conditions and test requirements have been harmonized with EN 13624;
- interfering substance for breweries, soft drinks, cosmetics and cleaning in place have been deleted. A sentence to allow additional interfering substance for specific applications has been added;
- the obligatory conditions (temperature and contact time) have been deleted. The text has been harmonized with EN 13624 keeping specified time intervals and temperature steps.

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, Turkey and the United Kingdom.

Introduction

This European Standard describes a suspension test for establishing whether a chemical disinfectant or antiseptic has or does not have a fungicidal or yeasticidal activity in the fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substance, i.e. conditions which may influence its action in practical situations.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to defined experimental conditions. However, for some applications the recommendations of use of a product may differ and therefore additional test conditions should be used.

This document is a preview generated by EVS

1 Scope

This document specifies a test method and the minimum requirements for fungicidal or yeasticidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water or - in the case of ready-to-use-products - with water. Products can only be tested at a concentration of 80 % or less as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products 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. The following areas are at least included:

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 ...);
- 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 ...);
- 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.

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

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*

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 terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

4 Requirements

The product shall demonstrate a reduction of at least a 4 decimal logarithm (lg) when diluted with hard water (5.2.2.7) or - in the case of ready-to-use products - with water (5.2.2.2) and tested in accordance with Clause 5 under simulated clean conditions (0,3 g/l bovine albumin solution - 5.2.2.8.2) or simulated dirty conditions (3 g/l bovine albumin solution - 5.2.2.8.3) according to its practical applications and under the other adopted test conditions as described in 5.5.1.1, Tables 1 and 2 here below.