

# SVENSK STANDARD

## SS-EN 1650:2008+A1:2013



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**Kemiska desinfektionsmedel och antiseptiska medel –  
Kvantitativt suspensionsprov för utvärdering av den fungicida  
verkan hos kemiska desinfektionsmedel och antiseptiska medel  
för användning i livsmedels-, industri-, hem- och  
institutionsmiljöer – Provningsmetod och krav (fas 2, steg 1)**

**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)**



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Denna standard ersätter SS-EN 1650:2008, utgåva 2.

The European Standard EN 1650:2008+A1:2013 has the status of a Swedish Standard. This document contains the official version of EN 1650:2008+A1:2013.

This standard supersedes the Swedish Standard SS-EN 1650:2008, edition 2.

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EUROPEAN STANDARD

EN 1650:2008+A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2013

ICS 71.100.35

Supersedes EN 1650:2008

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 5 April 2008 and includes Amendment 1 approved by CEN on 28 March 2013.

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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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (EN 1650:2008+A1:2013) 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 November 2013, and conflicting national standards shall be withdrawn at the latest by November 2013.

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 includes Amendment 1, approved by CEN on 2013-03-28.

This document supersedes A1 EN 1650:2008 A1.

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

This European Standard was revised to include the results of a collaborative trial (ANDISTAND), to correct obvious errors and ambiguities, to harmonize the structure and wording with other quantitative suspension tests of CEN/TC 216 (existing or in preparation), and to improve the readability of the standard and thereby make it more understandable.

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, 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 specifies 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.



## 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.

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- 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”.

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

NOTE 2 This method corresponds to a phase 2 step 1 test.

## 2 Normative references

The following referenced documents are indispensable for the application 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, mycobactericidal, sporicidal and fungicidal 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.

## 4 Requirements

The product shall demonstrate a reduction of at least a 4 decimal log (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 obligatory test conditions (one or two selected test organisms, 20 °C, 15 min).

The fungicidal activity shall be evaluated using the following two test organisms:

- *Candida albicans* (vegetative cells);

— *Aspergillus niger* (spores).

The yeasticidal activity shall be evaluated using the following test organism:

— *Candida albicans* (vegetative cells);

Where indicated, additional specific fungicidal or yeasticidal activity shall be determined applying other contact times, temperatures, interfering substances and test organisms (in accordance with 5.2.1, 5.2.2.8 and 5.5.1.1) 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 obligatory test conditions.

## 5 Test method

### 5.1 Principle

**5.1.1** A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of fungi (yeast cells or mould spores) in a solution of an interfering substance. The mixture is maintained at  $(20 \pm 1)$  °C for 15 min  $\pm$  10 s (obligatory test conditions). At the end of this contact time, an aliquot is taken, and the fungicidal and/or the fungistatic activity in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving fungi in each sample are determined and the reduction is calculated.

**5.1.2** The test is performed using the vegetative cells of *Candida albicans* and the spores of *Aspergillus niger* (fungicidal activity) or only the vegetative cells of *Candida albicans* (yeasticidal activity) as test organisms (obligatory test conditions).

**5.1.3** Additional and optional contact times and temperatures are specified. Additional test organisms can be used.

### 5.2 Materials and reagents

#### 5.2.1 Test organisms

The fungicidal activity shall be evaluated using the following strains as test organisms:<sup>1)</sup>

— *Candida albicans* ATCC 10231

— *Aspergillus niger* ATCC 16404

The yeasticidal activity shall be evaluated using only *Candida albicans*.

NOTE See annex A for strain references in some other culture collections.

The required incubation temperature for these test organisms is  $(30 \pm 1)$  °C (5.3.2.3).

If required for specific applications, additional strains may be chosen from, e.g. for breweries:

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<sup>1)</sup> The ATCC numbers are the collection numbers of strains supplied by the American Type Culture Collection (ATCC). This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.