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Standards

Irish Standard
I.S. EN 1650:2008+A1:2013

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)

I.S. EN 1650:2008+A1:2013

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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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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of an identical text or by endorsement, at the latest by November 2013, and conflicting national standards shall be withdrawn at the latest by November 2013.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.

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);

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