EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 1657

May 2023

ICS 71.100.35

Will supersede EN 1657:2016

English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - 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 vétérinaire - Méthode d'essai et prescriptions (ph

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der fungiziden oder levuroziden Wirkung chemischer Desinfektionsmittel und Antiseptika für den Veterinärbereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 216.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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

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European foreword

This document (prEN 1657:2023) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 1657:2016.

This document was revised to harmonize the preparation of the fungal spore suspension with other fungicidal tests of CEN/TC 216 and to incorporate amendments applicable to all European Standards.

An additional requirement has been added for the *Aspergillus* spore suspension and therefore results obtained using EN 1657:2005 and not fulfilling this additional requirement will need to be confirmed by repeating the tests using EN 1657:2015.

The test conditions for teat disinfectants have been added.

Introduction

This European Standard specifies a suspension test for establishing whether a chemical disinfectant or antiseptic has 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 substances, 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 need to 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 the veterinary area – i.e. in the breeding, husbandry, production, transport and disposal of all animals except when in the food chain following death and entry to the processing industry.

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 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 14885:2022, *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 14885:2022 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 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 Table 1 and Clause 5 under simulated low level soiling (3,0 g/l bovine albumin) or high level soiling (10 g/l yeast extract and 10 g/l bovine albumin) or 10 g/l skimmed milk for teat disinfectants or in additional test conditions.

Table 1 — Obligatory and additional test conditions

Test conditions	Fungicidal activity	Yeasticidal activity	Yeasticidal activity for teat disinfectants
Test organisms obligatory	*Aspergillus brasiliensis* *Candida albicans*	*Candida albicans*	*Candida albicans*
additional	any relevant test organism	any relevant test organism	any relevant test organism
Test temperature Minimum Maximum	At intervals of 5°C		
	5°C ± 1°C	5°C ± 1°C	20°C ± 1°C
	40°C ± 1°C	40°C ± 1°C	30°C ± 1°C
Contact time Minimum Maximum	At intervals of 30 s from 30 s to 5 min and at intervals of 5 min from 5 min to 120 min		
	1 min ± 5 s	1 min ± 5 s	1 min ± 5 s for post-milking teat disinfectants 30 s ± 5 s for pre-milking teat disinfectants
	120 min ± 10 s[a]	120 min ± 10 s[a]	30 min ± 10 s for post-milking teat disinfectants 3 min ± 10 s for pre-milking teat disinfectants
Interfering substance			
low level soiling high level soiling	3,0 g/l bovine albumin 10 g/l yeast extract plus 10 g/l bovine albumin	3,0 g/l bovine albumin 10 g/l yeast extract plus 10 g/l bovine albumin	Post milking: 10,0 g/l of milk powder Pre-milking: 3,0 g/l bovine albumin
additional	any relevant substance	any relevant substance	any relevant substance

The obligatory contact times for disinfectants stated in Table 1 were chosen to enable comparison of standard conditions.

NOTE For the additional conditions, the concentration defined as a result can be lower than the one obtained under the obligatory test conditions.

[a] The recommended contact time for the use of the product is within the responsibility of the manufacturer.

Any additional specific fungicidal activity shall be determined in accordance with 5.2.1 and 5.5.1.1 in order to take into account intended specific use conditions.