

Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 16437:2014 sisaldab Euroopa standardi EN 16437:2014 inglisekeelset teksti.	This Estonian standard EVS-EN 16437:2014 consists of the English text of the European standard EN 16437:2014.
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 26.02.2014.	Date of Availability of the European standard is 26.02.2014.
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:
Aru 10, 10317 Tallinn, Eesti; 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:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

ICS 71.100.35

English Version

**Chemical disinfectants and antiseptics - Quantitative surface test
for the evaluation of bactericidal activity of chemical disinfectants
and antiseptics used in veterinary area on porous surfaces
without mechanical action - Test method and requirements
(phase 2, step 2)**

Antiseptiques et désinfectants chimiques - Essai quantitatif
de surface pour l'évaluation de l'activité bactéricide des
antiseptiques et des désinfectants chimiques utilisés dans
le domaine vétérinaire sur des surfaces poreuses sans
action mécanique - Méthode d'essai et prescriptions (phase
2, étape 2)

Chemische Desinfektionsmittel und Antiseptika -
Quantitativer Oberflächenversuch zur Bestimmung der
bakteriziden Wirkung chemischer Desinfektionsmittel und
Antiseptika für den Veterinärbereich auf porösen
Oberflächen ohne mechanische Wirkung - Prüfverfahren
und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 30 November 2013.

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, 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 United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Requirements	5
5 Test method.....	6
5.1 Principle	6
5.2 Materials and reagents	7
5.2.1 Test organisms	7
5.2.2 Culture media and reagents	7
5.2.3 Test surface	10
5.3 Apparatus and glassware	10
5.3.1 General.....	10
5.3.2 Usual microbiological laboratory equipment	10
5.4 Preparation of test organism suspension and product test solutions	11
5.4.1 Test organism suspension (test and validation suspension)	11
5.4.2 Product test solution	13
5.5 Procedure for assessing the bactericidal activity of the product	13
5.5.1 General.....	13
5.5.2 Test procedure (Dilution-neutralisation method)	14
5.6 Experimental data and calculation.....	17
5.6.1 Explanation of terms and abbreviations	17
5.6.2 Calculation.....	18
5.7 Verification of methodology	21
5.7.1 General.....	21
5.7.2 Control of weighted mean counts	21
5.7.3 Basic limits	21
5.8 Expression of results and precision.....	22
5.8.1 Reduction	22
5.8.2 Control of active and non-active product test solution (5.4.2)	22
5.8.3 Limiting test organism and bactericidal concentration	22
5.8.4 Precision, repetitions	22
5.9 Interpretation of results – conclusion	22
5.9.1 General.....	22
5.9.2 Bactericidal activity for general purposes	23
5.9.3 Qualification for certain fields of application	23
5.10 Test report	23
Annex A (informative) Referenced strains in national collections	25
Annex B (informative) Neutralisers - Examples of neutralisers of the residual antimicrobial activity of chemical disinfectants and antiseptics	26
Annex C (informative) Graphical representations of dilution-neutralisation method	28
Annex D (informative) Example of a typical test report.....	32
Bibliography	37

Foreword

This document (EN 16437:2014) 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 August 2014 and conflicting national standards shall be withdrawn at the latest by August 2014.

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.

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 surface test for establishing whether a chemical disinfectant or antiseptic, for use on porous surfaces without mechanical action, in the veterinary area, has or does not have bactericidal activity under the laboratory conditions defined by this European Standard, which influence the action of disinfectants in practical use.

The laboratory test takes into account practical conditions of application of the product including pre-drying test organisms and interfering substances on a surface, contact time and temperature, 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 utilisation concentration of the chemical disinfectant or antiseptic, found by this test corresponds to the chosen experimental conditions. However, for some applications, the instructions of use of a product can differ and therefore additional test conditions need to be used.

1 Scope

This European Standard specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectants 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.

This European Standard applies to products that are used in the veterinary area on porous surfaces without mechanical action 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 2 test.

NOTE 3 This method cannot be used to evaluate the activity of products against mycobacteria or bacterial spores.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

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 at least a 4 decimal log (lg) reduction from a water control, when tested in accordance with Table 1 and Clause 5 under simulated soiling (3,0 g/l bovine albumin).