

ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 14349:2007

**Chemical disinfectants and antiseptics
- Quantitative surface test for the
evaluation of bactericidal activity of
chemical disinfectants and antiseptics**

Antiseptiques et désinfectants chimiques
- Essai quantitatif de surface pour
l'évaluation de l'activité bactéricide des
antiseptiques et des désinfectants

Chemische Desinfektionsmittel und
Antiseptika - Quantitativer
Oberflächenversuch zur Bestimmung der
bakteriziden Wirkung chemischer

10/2007



National Foreword

This European Standard EN 14349:2007 was adopted as Luxembourgish Standard ILNAS-EN 14349:2007.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

THIS PUBLICATION IS COPYRIGHT PROTECTED

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

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 non-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 non 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 nicht-porösen Oberflächen ohne mechanische Wirkung - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 24 May 2007.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 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..... | 6 |
| 5.2.1 Test organisms | 6 |
| 5.2.2 Culture media and reagents | 6 |
| 5.2.3 Test surface..... | 9 |
| 5.3 Apparatus and glassware | 9 |
| 5.3.1 General..... | 9 |
| 5.3.2 Usual microbiological laboratory equipment and, in particular, the following:..... | 9 |
| 5.4 Preparation of test organism suspensions and product test solutions | 10 |
| 5.4.1 Test organism suspensions | 10 |
| 5.4.2 Microbial test suspension..... | 11 |
| 5.4.3 Product test solutions..... | 11 |
| 5.5 Procedure for assessing the bactericidal activity of the product | 12 |
| 5.5.1 Experimental conditions (obligatory and additional)..... | 12 |
| 5.5.2 Test procedure | 12 |
| 5.6 Calculation and expression of results..... | 14 |
| 5.6.1 Calculation of viable counts (cfu/ml)..... | 14 |
| 5.6.2 Verification of methodology | 15 |
| 5.6.3 Expression of results | 15 |
| 5.7 Conclusion | 15 |
| 5.8 Test report | 16 |
| Annex A (normative) Validation of dilution neutralization | 18 |
| A.1 Principle..... | 18 |
| A.2 Preparation of microbial suspension and test surface..... | 18 |
| A.3 Preparation of product test solution..... | 18 |
| A.4 Test for validation | 18 |
| A.4.1 General..... | 18 |
| A.4.2 Procedure | 18 |
| A.4.3 Counting of the neutralizer toxicity and dilution neutralization controls | 19 |
| A.5 Validation..... | 19 |
| Annex B (informative) Suitable neutralizers | 20 |
| B.1 General..... | 20 |
| B.2 Neutralizers | 20 |
| Annex C (informative) Example of a typical test report..... | 22 |
| Annex D (informative) Referenced strains in national collections..... | 23 |
| Bibliography..... | 24 |

Foreword

This document (EN 14349:2007) 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 April 2008, and conflicting national standards shall be withdrawn at the latest by April 2008.

This document supersedes EN 14349:2004.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This European Standard specifies a surface test for establishing whether a chemical disinfectant or antiseptic in the veterinary area, on non-porous surfaces without mechanical action, 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 type and level of interfering substance can be selected as well as contact times and temperatures in addition to the levels specified in order to support recommendations for use under particular conditions. The method involves neutralization of the bactericidal activity at the moment of sampling by dilution into a previously validated neutralizer.

The conditions that shall be tested are intended to cover general purposes and to allow reference between laboratories and product types. For some applications, however, the recommendations 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 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.

This European Standard is applicable to products for use 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 Mycobacteria are the subject of a separate standard.

NOTE 2 This method corresponds to a Phase 2 Step 2 test.

2 Normative references

The following referenced document is 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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

product

chemical agent or formulation used as chemical disinfectant or antiseptic

3.2

bactericide

product that kills vegetative bacteria under defined conditions

NOTE The adjective derived from 'bactericide' is 'bactericidal'.

3.3

bactericidal activity

capability of a product to produce a reduction in the number of viable bacterial cells of relevant test organisms under defined conditions

4 Requirements

The product diluted in hard water (5.2.2.6) or – in the case of ready-to-use products – with water (5.2.2.2) when tested, in accordance with Clause 5, shall demonstrate at least a lg 4 reduction in viable counts from a water control when the test organisms are *Enterococcus hirae*, *Proteus vulgaris*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. The test is carried out under simulated low level (3,0 g/l bovine albumin) or high level soiling conditions (10 g/l yeast extract and 10 g/l bovine albumin) according to its practical applications and under the required test conditions (10 °C, 30 min, 4 referenced strains). Where appropriate additional and