

ILNAS

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

ILNAS-EN 14349:2004

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

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

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

08/2004



National Foreword

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English version

Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bacterial activity of chemical disinfectants and antiseptics used in veterinary field 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 16 January 2004.

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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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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

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Foreword

This document (EN 14349:2004) 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 February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

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

Introduction

This document describes a surface test for establishing whether a chemical disinfectant or antiseptic in the veterinary field, on non-porous surfaces without mechanical action, has or does not have bactericidal activity under the laboratory conditions defined by this document, 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 document specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation in hard water or – in the case of ready-to-use – with water.

This document is applicable to products for use in the veterinary field 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.

NOTE 1 Mycobacteria are the subject of a separate standard.

NOTE 2 This method corresponds to a Phase 2 Step 2 test (Annex E).

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 microbial strains used for the determination of bactericidal 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 which 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 organisms under defined conditions

4 Requirements

The product diluted in hard water (5.2.2.6) 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 optional contact times of 1 min, 5 min and 60 min and additional and optional temperatures of 4 °C, 20 °C and 40 °C are specified.