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English Version

Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the 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 exigences (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 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

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European foreword

This document (prEN 14349:2023) 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 14349:2012.

Data obtained using the former version of EN 14349 may still be used.

It was revised to correct obvious errors and ambiguities, to harmonize the structure and wording with other tests of CEN/TC 216 (existing or in preparation), and to improve the readability of the standard and thereby make it more understandable.

Introduction

This document specifies a surface test for establishing whether a chemical disinfectant or antiseptic has bactericidal activity in the area and 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 the 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 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.

The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used. This document applies to products that are used in the veterinary area for disinfecting non-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 This method corresponds to a Phase 2 Step 2 test.

This method excludes the evaluation of the activity of products against yeasts, fungal spores, mycobacteria and bacterial spores.

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, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

3.2 Symbols and abbreviations

c	is the sum of V_C-values taken into account
cfu	colony forming units
d	is the dilution taken into account, lower dilution factor
n	is the number of V_C-values taken into account
N	number of cells per ml in the test suspension
N_w	number of cfu recovered from the test surface in the water control
B	counting of the cfu in the neutralizer control
Na	number of cfu recovered from the test surface in the test
C	counting of the cfu in the method validation

N_{ts} number of colony forming units remaining on the test surface

R reduction

V is the volume of the inoculated into the plate expressed in ml

Nv is the validation suspension

4 Requirements

The product shall demonstrate at least a 4 decimal log (lg) reduction when diluted with hard water (5.2.2.6) 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 g/l bovine albumin) or high level soiling (10 g/l yeast extract and 10 g/l bovine albumin) on a surface.

Table 1 - Test conditions

Test conditions	**Bactericidal activity on non-porous surfaces without mechanical action in the veterinary area**
Minimum spectrum of test organisms	*Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus*
additional	any relevant test organism
Test temperature Minimum Maximum	According to the manufacturer's recommendation but between 4 °C ± 1 °C 40 °C ± 1 °C At intervals of 5°C
Contact time Minimum Maximum	 1 min ± 5 s 120 min ± 10 s At intervals of 30 s from 30 s to 5 min and at intervals of 5 min from 5 min to 120 min
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
additional	any relevant substance
The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. NOTE For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.	