SLOVENSKI STANDARD
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Kemična razkužila in antiseptiki - Kvantitativni površinski preskus brez mehanskega delovanja za vrednotenje razkužil za seske v veterini - Preskusna metoda in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area - Test method and requirements (phase 2 step 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Oberflächenversuch zur Beurteilung von Zitzendesinfektionsmittel für den Veterinärbereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface pour l'évaluation des désinfectants de trayons utilisés dans le domaine vétérinaire - Méthode d'essai et prescriptions (phase 2, étape 2)

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Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area - Test method and requirements (phase 2 step 2)

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Chemische Desinfektionsmittel und Antiseptika - Quantitativer Oberflächenversuch zur Beurteilung von Zitzendesinfektionsmittel für den Veterinärbereich - 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
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Contents

Page

European foreword

This document (prEN 17422:2024) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document will supersede EN 17422:2022.

This document was revised to harmonize the milk soiling levels, clarify terms and abbreviations and provide clearer definitions around the calculations.

Introduction

This document specifies a surface test for establishing whether a chemical disinfectant or antiseptic has a bactericidal 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 bactericidal activity of teat disinfectants that form a homogeneous, physically stable preparation when diluted with hard water or — in the case of ready-to-use products — with water.

This method applies to teat disinfectants that are used on teat skin without mechanical action as pre-milking and/or post-milking teat disinfectants in the veterinary area, e.g. in the breeding, husbandry, production, veterinary care facilities, transport and disposal of all animals except when in the food chain following death and entry into processing industry.

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.

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 and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electromedical: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp/

3.1 Symbols and abbreviated terms

N	Test suspension
Na	Test suspension + Interference substance
Nv	Validation suspension
Nw	Water control
B	Control B
C	Control C
Vc	Viable count
NUw	Used water
NUd	Used disinfectant
Nws	Water control surface
Nts	Test surface

4 Requirements

The product shall demonstrate at least a 4 decimal log (lg) (post-milking disinfectant) or 3 decimal log (lg) (pre-milking disinfectant) reduction from a water control, when tested in accordance with Table 1 and Clause 5 under simulated soiling (10,0 g/l skimmed milk for post-milking teat disinfectants, 3,0 g/l bovine albumin for pre-milking teat disinfectants).

Table 1 — Test Conditions

Test Conditions	**Bactericidal activity on synthetic skin without mechanical action**	
Minimum spectrum of test organisms	*Escherichia coli* *Staphylococcus aureus*	
Additional	Any relevant test organism	
Test temperature	30 °C ± 1 °C	
Contact time Minimum contact time	Pre-milking teat disinfectants 30 s ± 5 s	Post-milking teat disinfectants 1 min ± 5 s
Maximum contact time	Pre-milking teat disinfectants 3 min ± 10 s	Post-milking teat disinfectants 5 min ± 10 s
Other contact times may be selected at intervals of 30 s for contact times up to 1 min and at intervals of 1 min for contact times > 1 min		
Interfering substance Post-milking teat disinfectants Pre-milking teat disinfectants	10,0 g/l milk powder 3,0 g/l bovine albumin	

5 Test method

5.1 Principle

A test suspension of bacteria mixed with interfering substance (5.2.2.7) is inoculated onto a synthetic skin test surface and maintained at 30 °C for a period of conditioning.

After this conditioning time, the test surface is immersed in the product or dilutions of the product at 30 °C for 30 s soaking time, removed, and incubated at 30°C for the remaining defined period of time specified in Table 1. At the end of that contact time, the surface is transferred into neutralizer so that the action of the disinfectant is immediately neutralized. At the same time an aliquot of the used disinfectant is sampled and neutralized as well.

The bacteria are removed from the surface by ultrasound treatment. The numbers of surviving bacteria which can be recovered from the surface are determined quantitatively. The numbers of surviving bacteria in the used disinfectant are determined quantitatively.

The number of bacteria on a surface treated with water in place of the disinfectant is also determined and the reduction is calculated.

5.2 Materials and reagents

5.2.1 Test organisms

The bactericidal activity shall be evaluated using the following strains as test organisms:

- *Escherichia coli*
- *Staphylococcus aureus*

NOTE Refer to Annex A for strain references in other culture collections.

The required incubation temperature for these test organisms is 36 °C ± 1 °C or 37 °C ± 1 °C (5.3.2.3).

The same temperature (either 36 °C or 37 °C) shall be used for all growth incubations performed during a test and its control and validation.

If additional test organisms are used, they shall be incubated under optimum growth conditions (temperature, time, atmosphere, media) noted in the test report. If the additional test organisms selected do not correspond to the specified strains, their suitability for supplying the required inocula shall be verified. If these additional test organisms are not classified at a reference centre, their identification characteristics shall be stated. In addition, they shall be held by the testing laboratory or national culture collection under a reference for five years.

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this document refer to the anhydrous salts. Hydrated forms may be used as an alternative, but the weights required shall be adjusted to allow for consequent molecular weight differences.

The reagents shall be of analytical grade and/or appropriate for microbiological purposes. They shall be free from substances that are toxic or inhibitory to the test organisms.

If additional strains do not grow on the media (5.2.2.3) or cannot be used with diluent (5.2.2.4) additional media shall be used and shall be reported as well as additional incubation conditions.

To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturers' instructions relating to the preparation of these products should be rigorously followed.

A ready-to-use media may be used if it complies with the required specification.

For each culture medium and reagent, a time limitation for use should be fixed.

5.2.2.2 Water

The water shall be freshly glass-distilled water and not demineralized water. If distilled water of adequate quality is not available, water for injections (see bibliographic reference [2]) may be used.

Sterilize in the autoclave [5.3.2.1 a)]. Sterilization is not necessary if the water is used e.g. for preparation of culture media and subsequently sterilized.

5.2.2.3 Tryptone soya agar (TSA)

Tryptone soya agar, consisting of:

Tryptone, pancreatic digest of casein	15,0 g;
Soya peptone, papaic digest of soybean meal	5,0 g;
Sodium chloride (NaCl)	5,0 g;
Agar	15,0 g;
Water (5.2.2.2) to	1 000,0 ml.

Sterilize in the autoclave [5.3.2.1 a)].

After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at (20 ± 1) °C.

In case of encountering problems with neutralization (5.5.1.2 and 5.5.1.3), it may be necessary to add neutralizer to the TSA. Annex B, Table B.1 gives guidance on the neutralizers that may be used. It is recommended not to use a neutralizer that causes opalescence in the agar.

5.2.2.4 Diluent

Tryptone sodium chloride solution, consisting of:

Tryptone, pancreatic digest of casein		1,0 g;
Sodium chloride (NaCl)		8,5 g;
Water (5.2.2.2)	to	1 000,0 ml

Sterilize in the autoclave [5.3.2.1 a)].

After sterilization, the pH of the diluent shall be equivalent to 7,0 ± 0,2 when measured at (20 ± 1) °C.

5.2.2.5 Neutralizer

The neutralizer shall be validated for the product being tested in accordance with 5.5.1.2. The neutralizer shall be sterile.

NOTE Information on neutralizers that have been found to be suitable for some categories of products is given in Annex B.

5.2.2.6 Hard water for dilution of products

For the preparation of 1 000 ml of hard water, the procedure is as follows:

— Prepare solution A: dissolve 19,84 g magnesium chloride ($MgCl_2$) and 46,24 g calcium chloride ($CaCl_2$) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.7) or in the autoclave [5.3.2.1a)]. Autoclaving – if used - may cause a loss of liquid. In this case make up to 1 000 ml with water (5.2.2.2) under aseptic conditions. Store the solution in the refrigerator (5.3.2.8) for no longer than one month.

— Prepare solution B: dissolve 35,02 g sodium bicarbonate ($NaHCO_3$) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.7). Store the solution in the refrigerator (5.3.2.8) for no longer than one week.

Place 600 ml to 700 ml of water (5.2.2.2) in a 1 000 ml volumetric flask (5.3.2.12) and add 6,0 ml of solution A, then 8,0 ml of solution B. Mix and dilute to 1 000 ml with water (5.2.2.2). The pH of the hard water shall be 7,0 ± 0,2, when measured at (20 ± 1) °C (5.3.2.4). If necessary, adjust the pH by using a solution of approximately 40 g/l (about 1 mol/l) of sodium hydroxide (NaOH) or approximately 36,5 g/l (about 1 mol/l) of hydrochloric acid (HCl).

The hard water shall be freshly prepared under aseptic conditions and used within 12 h.

NOTE When preparing the product test solutions (5.4.2), the addition of the product to the hard water produces different final water hardness in each test tube. In any case the final hardness expressed as calcium carbonate ($CaCO_3$) is in the test tube lower than 375 mg/l.

5.2.2.7 Interfering substances

5.2.2.7.1 General

Interfering substances shall be sterile and prepared at 2 times the final concentration in the test.

NOTE The term ‘interfering substance’ is used even if it contains more than one substance.

5.2.2.7.2 Skimmed milk

Prepare a solution of 20 g milk-powder guaranteed free of antibiotics and additives in 1 000 ml water (5.2.2.2).