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SWEDISH STANDARDS INSTITUTE

Kemiska desinfektionsmedel och antiseptiska medel – Hygienisk handdesinfektion – Provningsmetod och krav (fas 2/steg 2)

Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2)

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Europastandarden EN 1500:2013 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 1500:2013.

Denna standard ersätter SS-EN 1500, utgåva 1.

The European Standard EN 1500:2013 has the status of a Swedish Standard. This document contains the official version of EN 1500:2013.

This standard supersedes the Swedish Standard SS-EN 1500, edition 1.

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Denna standard är framtagen av kommittén för Sterilisering av medicintekniska produkter, SIS/TK 349.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1500

April 2013

ICS 11.080.20; 71.100.35

Supersedes EN 1500:1997

English Version

Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)

Antiseptiques et désinfectants chimiques - Traitement hygiénique de mains par frictions - Méthode d'essai et prescriptions (phase 2/étape 2)

Chemische Desinfektionsmittel und Antiseptika - Hygienische Händedesinfektion - Prüfverfahren und Anforderungen (Phase 2/Stufe 2)

This European Standard was approved by CEN on 1 March 2013.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN 1500:2013: E

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Foreword

This document (EN 1500:2013) 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 October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.

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.

This document supersedes EN 1500:1997.

This document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonise 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.

The following technical changes have been made:

— Neutralization (5.5.1.2).

— The number of volunteers (5.5.1.4).

— The statistical evaluation (5.8).

— The annexes have been completely revised.

Data obtained using the former version of EN 1500 may still be used, if it is supplemented by data on neutralization, additional results from more volunteers and the new statistical evaluation of the “mixed” (old and new) set of data. The additional results will be obtained preferably in the same laboratory and with volunteers not having participated in the previous (“old”) study. If the neutralizer used in the test using the former version is not sufficiently neutralizing, a complete new test will be run. The changed procedure in Annex A is regarded as having no (or negligible) influence on the results.

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.

1 Scope

This European Standard specifies a test method simulating practical conditions for establishing whether a product for hygienic handrub reduces the release of transient microbial flora on hands when rubbed onto the artificially contaminated hands of volunteers.

NOTE 1 Attention is drawn to the fact that tests on human volunteers are the subject of legal provisions in certain European countries/regions.

This European Standard applies to products for hygienic handrub for use in areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities and in dental institutions,

— in clinics of schools, of kindergartens and of nursing homes;

and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patient.

EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

NOTE 2 This method corresponds to a phase 2, step 2 test.

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

When tested in accordance with Clause 5, the mean reduction of the release of the test organism *Escherichia coli K12* achieved by the hygienic handrub with the product under test shall be at least not inferior to that achieved by a specified reference hygienic handrub (60 % volume concentration of propan-2-ol).

5 Test method

5.1 Principle

Hands of volunteers are artificially contaminated with test organisms. The number of test organisms released from their fingertips into sampling fluids is assessed before and after the hygienic handrub. The ratio of the

two resulting values represents a measure for the antimicrobial activity of the product tested. The necessary precision is achieved by repeating the test on 18 to 22 volunteers. To compensate for extraneous influences it is compared with the reduction obtained by a reference handrub, which is performed with the same volunteers, on the same day and under comparable environmental conditions.

Prior to the test, a suitable neutralizer is validated. The neutralizer is used as a sampling fluid for recovering the test organisms after the hygienic handrub to ensure that the bactericidal and/or bacteriostatic activity in the sampling fluids is neutralized or suppressed.

5.2 Materials and reagents

5.2.1 Test organism

Escherichia coli K12 NCTC 10538; CIP 54.117; NCIMB 10083[1)]

NOTE This test organism has been specifically chosen to meet health and safety guidance and ethical committee considerations. It is a K12 strain of E. coli of normal flora origin internationally recognised as being non-pathogenic. According to the UK catalogue of the National Collections of Industrial & Marine Bacteria (see [2]), NCIMB strain 10083 is classified as a risk group 1 organism. The German Safety Ordinance on Gene Technology [3] also assigns the K12 strain to group 1. Directive 93/88/EEC [4] (Annex III to Directive 90/679/EEC [5]) explicitly states that non-pathogenic strains of Escherichia coli are excluded from the group 2 assignment.

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this European Standard 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. To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed. 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 demineralised water. If distilled water of adequate quality is not available, water for injections (see bibliographic reference [1]) may be used.

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

NOTE See 5.2.2.7 for the procedure to prepare hard water.

5.2.2.3 Tryptone soya agar and tryptone soya selective agar

a) Tryptone Soya Agar (TSA)

Tryptone soya agar, consisting of:

[1)] The NCTC, CIP and NCIMB numbers are the collection numbers of this strain supplied by these cultures collections. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of the product named.

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

Sterilise in the autoclave [5.3.2.1 a)]. After sterilisation, the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at (20 ± 1) °C.

NOTE 1 TSA is used for preparing and counting N, N_v and N_{vB} (5.4.1.4, 5.4.1.5).

b) Tryptone Soya Selective Agar (TSSA)

Tryptone soya selective 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
Sodium-desoxycholate	0,5 g
Agar	15,0 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilise in the autoclave [5.3.2.1 a)]. After sterilisation, the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at (20 ± 1) °C.

NOTE 2 TSSA is used for quantitative cultures of the sampling fluids and their dilutions (5.5.3.2, 5.5.3.3.4).

5.2.2.4 Tryptone Soya Broth (TSB)

Tryptone soya broth, 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
Water (5.2.2.2)	to 1 000,0 ml

Sterilise in the autoclave [5.3.2.1 a)]. After sterilisation, the pH of the medium shall be equivalent to 7,0 ± 0,2 when measured at (20 ± 1) °C.

5.2.2.5 Neutralizer

The neutralizer shall be chosen, controlled and validated for the product under test in accordance with 5.5.1.2, 5.5.2.1 and 5.5.2.2. Only neutralizers using TSB (5.2.2.4) as diluent are allowed. It shall be sterile. The reference product is neutralized by dilution only.

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 Diluted soft soap

Linseed oil	50,0 parts by weight
Potassium hydroxide [1]	9,5 parts by weight
Ethanol (min. 95 %) [1]	7,0 parts by weight
Hot distilled water (75 ± 5) °C	as needed

Prepare a solution of 9,5 parts potassium hydroxide in 15 parts water (5.2.2.2) and add 50 parts linseed oil. Heat up to approximately 70 °C while constantly stirring. Add the ethanol and continue heating while stirring until the saponification process is completed and a sample dissolves clearly in water and almost clearly in alcohol. The weight of the soft soap is then brought up to 100 parts by addition of water (5.2.2.2), and heated up to (75 ± 5) °C to dilute the soft soap. Take 200 g of the soft soap, fill up to 1 000 g with water (5.2.2.2) and sterilise in the autoclave (5.5.2.1). The pH of the final diluted soft soap shall range between 10,0 and 11,0.

For quality control of the soft soap, see Annex D.

5.2.2.7 Hard water for dilution of products

For the preparation of 1 l 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. Sterilise by membrane filtration (5.3.2.7) or in the autoclave [5.3.2.1 a)]. Autoclaving – if used - may cause a loss of liquid. In this case make up to 1000 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 1000 ml. Sterilise 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 (5.3.2.9) of solution A, then 8,0 ml of solution B. Mix and dilute to 1000 ml with water (5.2.2.2). The pH of the hard water shall be 7,0 ± 0,2, when measured at 20 °C ± 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 a different final water hardness in each test tube. In any case, the final hardness, expressed as calcium carbonate ($CaCO_3$) in the test tube, is lower than 375 mg/l.

5.2.2.8 Propan-2-ol as reference handrub [52,3 % (weight concentration) corresponding to 60 % (volume concentration) at 20 °C]

Fill 471 g propan-2-ol [1] with a purity of min. 99,5 % *V/V* (determined by gas chromatography; density 0,785) in a 1000 ml flask equipped with a glass stopper on the weighing platform of a scale (precision 0,1 g). Add 429 g water (5.2.2.2). This will give a volume of approximately 1 000 ml. Close the flask with the matching glass stopper and shake the contents of the flask thoroughly.

NOTE This solution can be kept indefinitely at approximately room temperature if protected from light.