

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

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British Standard

ICS 11.080

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee IH/57, Chemical disinfectants and antiseptics, which has the responsibility to:

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 16 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Board, was published under the authority of the Standards Board and comes into effect on 15 November 1997

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Amendments issued since publication

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Descriptors: Disinfectants, chemical compounds, hygiene, hand (anatomy), tests, contamination, antibacterial activity, neutralizing, counting, micro-organisms

English version

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

Antiseptiques et désinfectants chimiques — Traitement hygiénique des 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)

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Foreword

This European Standard has been prepared by the 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of an identical text or by endorsement, at the latest by January 1998, and conflicting national standards shall be withdrawn at the latest by January 1998.

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

Annex A is normative. Annex B, Annex C, Annex D and Annex E are informative.

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

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1 Scope

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

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.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 12054, *Chemical disinfectants and antiseptics — Products for hygienic and surgical handrub and handwash — Bactericidal activity — Test method and requirements (phase 2/step 1)*.

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1

product (for chemical disinfection and/or antiseptics)

chemical agent or formulation used as a chemical disinfectant and/or antiseptic (EN 1040)

3.2

hygienic handrub

postcontamination treatment procedure that involves rubbing hands without the addition of water, using a bactericidal preparation directed against transient microorganisms to prevent their transmission regardless of the resident skin flora

3.3

prevalue

number of colony forming units (cfu) sampled from hands before treatment

3.4

postvalue

number of colony forming units (cfu) sampled from hands after treatment

3.5

reduction factor (RF)

ratio of prevalues and postvalues, generally expressed by decimal logarithms:

$$\log_{10} \text{RF} = \log_{10} \text{prevalue} - \log_{10} \text{postvalue}$$

4 Requirements

When tested in accordance with clause 5, the mean reduction of the release of test organisms achieved by the hygienic handrub product shall not be significantly smaller than that achieved by a reference handrub (R) (see 5.6.4.2) with propan-2-ol 60 % (V/V).

Products under test shall at least have a bactericidal activity as specified in prEN 12054.