

Chemical disinfectants and antiseptics — Basic bactericidal activity — Test method and requirements (phase 1)

The European Standard EN 1040:1997 has the status of a
British Standard

ICS 11.080; 67.020

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee IH/57, Chemical disinfectants and antiseptics, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Public Analysts
- British Association for Chemical Specialities
- Campden and Chorleywood Food Research Association
- Consumer Policy Committee of BSI
- Department of Health
- Institute of Trading Standards Administration
- Ministry of Agriculture, Fisheries and Food
- Ministry of Defence
- Public Health Laboratory Service
- Society for Applied Bacteriology
- Society of Chemical Industry

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

© BSI 11 September 2002

The following BSI references relate to the work on this standard:
Committee reference IH/57
Draft for comment 93/502729 DC

ISBN 0 580 28387 9

Amendments issued since publication

Amd. No.	Date	Comments
13799 Corrigendum No. 1	11 September 2002	Addition of supersession details in national foreword

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 1040	5

National foreword

This British Standard has been prepared by Technical Committee IH/57 and is the English language version of EN 1040:1997, *Chemical disinfectants and antiseptics — Basic bactericidal activity — Test method and requirements (phase 1)*, published by the European Committee for Standardization (CEN). It supersedes BS 541:1985 which will be withdrawn.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct applications.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 23 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

ICS 11.080; 67.020

Descriptors: Disinfectants, chemical compounds, tests, determination, antibacterial activity, preparation, filtration analysis, neutralization method, dilution, culture media

English version

Chemical disinfectants and antiseptics — Basic bactericidal activity — Test method and requirements (phase 1)

Antiseptiques et désinfectants chimiques —
Activité bactéricide de base —
Méthode d'essai et prescriptions (phase 1)

Chemische Desinfektionsmittel und
Antiseptika — Bakterizide Wirkung
(Basistest) — Prüfverfahren und
Anforderungen (Phase 1)

This European Standard was approved by CEN on 1997-01-05. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

© 1997 Copyright reserved to CEN members

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 216, Chemical disinfectants and antiseptics, the Secretariat of which is held by AFNOR.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different fields of application are in preparation.

Annex A is normative.

Annex B, Annex C, Annex D, Annex E, Annex F and Annex G are informative.

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 August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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

Contents

	Page
Foreword	2
Introduction	5
1 Scope	5
2 Normative references	5
3 Definitions	5
3.1 product (for chemical disinfection and/or antisepsis)	5
3.2 bactericide	5
3.3 bactericidal activity (EN 1040)	5
4 Requirements	5
5 Test method	6
5.1 Principle	6
5.2 Materials and reagents	6
5.3 Apparatus and glassware	7
5.4 Preparation of bacterial suspensions and test solutions	8
5.5 Procedure	9
5.6 Calculation and expression of results	11
5.7 Conclusion	13
5.8 Test report	14
Annex A (normative) Validation of dilution-neutralization and membrane filtration methods	15
Annex B (informative) Neutralizers	17
Annex C (informative) Rinsing liquids	17
Annex D (informative) Example of a typical test report	18
Annex E (informative) Referenced strains in national collections	20
Annex F (informative) Precision of the test result	20
Annex G (informative) Information on the application and interpretation of European standards on chemical disinfectants and antiseptics	23

	Page
Table D.1 — Verification of the methodology and validation of dilution-neutralization method for the test concentration of 8 g/l of the test product as received	19
Table D.2 — Verification of the methodology and validation of membrane filtration method for the test concentration of 8 g/l of the test product as received	19
Table D.3 — Test results: Example for dilution-neutralization method	19
Table D.4 — Test results: Example for membrane filtration method	20
Table F.1 — Percentage of laboratories having more than half of their valid replicates with at least a 10^5 reduction at a given phenol concentration	20
Table F.2 — Percentage of laboratories having more than half their valid replicates with at least a 10^5 reduction at a given benzalkonium chloride concentration	20
Table F.3 — Standard deviation (σ) of $\log_{10}$ reduction — by method and product	21
Table F.4	22

Introduction

This European Standard describes a suspension test method for establishing whether a chemical disinfectant or antiseptic has or does not have a bactericidal activity under the laboratory conditions defined by this European Standard. If a product complies with the test requirements, it can be considered as possessing a bactericidal activity. The acceptability of a product as a chemical disinfectant or antiseptic for a defined purpose cannot be determined from this test method. Chemical disinfectants and antiseptics are subjected to further testing by relevant tests according to European Standards to evaluate their activity under conditions appropriate to their intended use¹⁾.

There is no evidence that the strains used in this standard are virulent.

1 Scope

This European Standard specifies a test method (phase 1) and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation in water. This European Standard is applicable to products for use in agricultural (but not crop protection), domestic service, food hygiene and other industrial fields, institutional, medical and veterinary applications.

NOTE 1 Using this European Standard it is not possible to determine the bactericidal activity of the undiluted product as some dilution is always produced by adding the inoculum.

NOTE 2 This European Standard does not evaluate the activity of a product for an intended use. More specific test methods described in European Standards (see Introduction) are used for further assessment of the efficacy of chemical disinfectants and antiseptics for a defined purpose.

NOTE 3 This method corresponds to a phase 1 test (see Annex G).

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 12353, *Chemical disinfectants and antiseptics — Preservation of microbial strains used for the determination of bactericidal and fungicidal activity*.

3 Definitions

For the purposes of this European Standard the following definitions apply.

3.1

product (for chemical disinfection and/or antiseptics)

chemical agent or formulation used as a 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 (EN 1040)

capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under conditions defined by this European Standard

4 Requirements

The product, when tested in accordance with clause 5, shall demonstrate at least a 10⁵ log reduction in viable counts when the test organism is *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

¹⁾ CEN/TC will develop relevant tests.