

STN	Chemické dezinfekčné prípravky Kvantitatívna suspenzná skúška na vyhodnotenie sporicídnej aktivity chemických dezinfekčných prípravkov používaných v potravinárstve, priemysle, v domácnostiach a inštitúciách Skúšobná metóda a požiadavky (fáza 2, krok 1)	STN EN 13704 85 7019
------------	---	--

Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/18

Obsahuje: EN 13704:2018

Oznámením tejto normy sa ruší
STN EN 13704 (85 7019) z apríla 2003

127498

EUROPEAN STANDARD

EN 13704

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2018

ICS 71.100.35

Supersedes EN 13704:2002

English Version

Chemical disinfectants - Quantitative suspension test for
the evaluation of sporicidal activity of chemical
disinfectants used in food, industrial, domestic and
institutional areas - Test method and requirements (phase
2, step 1)

Désinfectants chimiques - Essai quantitatif de
suspension pour l'évaluation de l'activité sporicide des
désinfectants chimiques utilisés dans le domaine de
l'agro-alimentaire, dans l'industrie, dans les domaines
domestiques et en collectivité - Méthode d'essai et
prescriptions (phase 2, étape 1)

Chemische Desinfektionsmittel - Quantitativer
Suspensionversuch zur Bestimmung der sporiziden
Wirkung chemischer Desinfektionsmittel in den
Bereichen Lebensmittel, Industrie, Haushalt und
öffentliche Einrichtungen - Prüfverfahren und
Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 16 March 2018.

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

CEN members are the national standards bodies of 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN 13704:2018 (E)

Contents

Page

European foreword.....	4
Introduction	5
1 Scope.....	6
2 Normative references.....	7
3 Terms and definitions	7
4 Requirements	8
5 Test method	8
5.1 Principle	8
5.2 Materials and reagents.....	9
5.2.1 Test organisms.....	9
5.2.2 Culture media and reagents	9
5.3 Apparatus and glassware	11
5.3.1 General.....	11
5.3.2 Usual microbiological laboratory equipment and, in particular, the following.....	11
5.4 Preparation of spore test suspension and test solutions	12
5.4.1 Spore suspensions	12
5.4.2 Product test solution.....	14
5.5 Procedure.....	15
5.5.1 Choice of experimental conditions	15
5.5.2 Test procedure for assessing the sporicidal effect of the product	15
5.5.3 Validation of dilution neutralization and membrane filtration method	17
5.6 Calculation and expression of results.....	17
5.6.1 Overview of the different suspensions and test mixtures.....	17
5.6.2 Calculation.....	18
5.7 Verification of methodology.....	23
5.7.1 General.....	23
5.7.2 Control of weighted mean counts.....	23
5.7.3 Basic limits	23
5.7.4 Expression of results.....	24
5.8 Conclusion.....	24
5.9 Test report.....	24
Annex A (normative) Preparation of <i>Bacillus subtilis</i> and <i>Bacillus cereus</i> spore stock suspensions.....	26
A.1 Material and reagents.....	26
A.2 Preparation of <i>Bacillus</i> spore stock suspensions	26
Annex B (normative) Validation of dilution-neutralization and membrane filtration methods	28
B.1 Principle	28
B.2 Preparation of spore suspension	28
B.3 Preparation of product test solution.....	28
B.4 Test for validation.....	28
B.4.1 Dilution-neutralization method.....	28

B.4.1.1 General	28
B.4.1.2 Validation	29
B.4.2 Membrane filtration method	30
B.4.2.1 General	30
B.4.2.2 Validation	30
B.5 Validation	32
Annex C (informative) Preparation of <i>Clostridium sporogenes</i> spore stock suspension	33
C.1 Culture media and reagents	33
C.2 Apparatus and glassware	34
C.3 Preparation of regenerated media and incubation conditions	34
C.4 Preparation of <i>Clostridium</i> spore stock suspension	34
Annex D (informative) Neutralizers and rinsing liquids	36
Annex E (informative) Example of a typical test report	38
Annex F (informative) Referenced strains in national collections	40
F.1 <i>Bacillus subtilis</i>	40
F.2 <i>Bacillus cereus</i>	40
F.3 <i>Clostridium sporogenes</i>	40
Bibliography	41

EN 13704:2018 (E)**European foreword**

This document (EN 13704:2018) 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 January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13704:2002.

It was revised in order to include the spore susceptibility controls, to better detail spore preparation procedures and to harmonize counting and elaboration of the results with the other CEN/TC 216 current standards.

EN 13704:2018 includes the following changes compared to EN 13704:2002:

- inclusion of spore suspension susceptibility controls;
- modification of spore preparation procedures;
- inclusion of spore maturation time;
- harmonization of counting and elaboration of the results with the other CEN/TC 216 current standards;
- deletion of obligatory conditions for contact time and temperature;
- inclusion of minimum and maximum conditions for contact time and temperature;
- inclusion of dirty conditions.

Results obtained with the previous version are not valid.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard describes a suspension test method for establishing whether a chemical disinfectant has or does not have a sporicidal activity in the fields described in Clause 1.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, in suspension, etc.) reflect parameters which are found in practical situations including conditions which can influence the action of disinfectants. Each utilization concentration found from this test corresponds to defined experimental conditions.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types.

However for some applications the recommendations of use of a product can differ and therefore additional test conditions need to be used.

EN 13704:2018 (E)**1 Scope**

This document specifies a test method (phase 2/step 1) and the minimum requirements for sporicidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation in hard water and that are used in food, industrial, domestic and institutional areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas.

This European Standard applies at least to the following:

- a) processing, distribution and retailing of:
 - 1) food of animal origin:
 - milk and milk products;
 - meat and meat products;
 - fish, seafood, and related products;
 - eggs and egg products;
 - animal feeds;
 - etc.;
 - 2) food of vegetable origin:
 - beverages;
 - fruits, vegetables and derivatives (including sugar, distillery, etc.);
 - flour, milling and baking;
 - animal feeds;
 - etc.;
- b) institutional and domestic areas:
 - catering establishments;
 - public areas;
 - public transports;
 - schools;
 - nurseries;
 - shops;
 - sports rooms;
 - waste containers (bins, etc.);

- hotels;
 - dwellings;
 - clinically non sensitive areas of hospitals;
 - offices;
 - etc.;
- c) other industrial areas:
- packaging material;
 - biotechnology (yeast, proteins, enzymes, etc.);
 - pharmaceutical;
 - cosmetics and toiletries;
 - textiles;
 - space industry, computer industry;
 - etc.

Using this European Standard, it is not possible to determine the sporicidal activity of undiluted product as some dilution is always produced by adding the inoculum and interfering substance. Products can only be tested at a concentration of 80 % or less.

NOTE The method described is intended to determine the activity of commercial formulations or active substances on spores in the conditions in which they are used.

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN