

STN	Chemické dezinfekčné a antiseptické prípravky Chemicko-tepelná dezinfekcia bielizne Skúšobná metóda a požiadavky (fáza 2, krok 2)	STN EN 16616 85 7054
------------	--	--

Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)

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. 11/22

Obsahuje: EN 16616:2022

Oznámením tejto normy sa ruší
STN EN 16616 (85 7043) z januára 2016

EUROPEAN STANDARD

EN 16616

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2022

ICS 11.080.20

Supersedes EN 16616:2015

English Version

**Chemical disinfectants and antiseptics - Chemical-thermal
textile disinfection - Test method and requirements (phase
2, step 2)**

Désinfectants chimiques et antiseptiques - Désinfection
thermochimique du textile - Méthode d'essai et
prescriptions (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika -
Chemothermische Wäschedesinfektion - Prüfverfahren
und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 27 June 2022.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, 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 16616:2022 (E)

Contents	Page
European foreword.....	4
Introduction	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Requirements	8
5 Test methods	9
5.1 Principle	9
5.2 Materials and reagents.....	9
5.2.1 Test organisms.....	9
5.2.2 Culture media and reagents	10
5.3 Apparatus and glassware	12
5.3.1 General.....	12
5.3.2 Usual microbiological laboratory equipment.....	13
5.4 Preparation of test organism suspensions (test suspension).....	15
5.4.1 General.....	15
5.4.2 Preservation and stock cultures of test organisms.....	15
5.4.3 Working culture and test organisms.....	16
5.4.4 Test suspension (<i>N</i>).....	16
5.4.5 Inoculation of the carriers	20
5.5 Procedure for assessing the microbicidal activity of the product.....	21
5.5.1 General.....	21
5.5.2 Test procedure	22
5.6 Experimental data and calculation	24
5.6.1 Explanation of terms and abbreviations	24
5.6.2 Calculation.....	25
5.7 Verification of methodology.....	27
5.7.1 General.....	27
5.7.2 Control of weighted mean counts.....	28
5.7.3 Basic limits	28
5.8 Expression of results and precision	28
5.8.1 Reduction.....	28
5.8.2 Repetitions	29
5.9 Interpretation of results – conclusion	29
5.9.1 General.....	29
5.9.2 Microbicidal activity	29
5.10 Test report.....	30
Annex A (informative) Referenced strains in national collections	32
Annex B (informative) Suitable neutralizers	34
B.1 General.....	34
B.2 Neutralizers.....	34
B.3 Neutralizer added to the agar for counting	35
Annex C (informative) Graphical representations of the test method.....	36

Annex D (informative) Example of washing machine specification.....	37
Annex E (informative) Preparation of hard water for using in the test and reference procedures.....	38
Annex F (informative) Test report (example).....	39
Annex G (informative) Example for loading the washing machine	46
Bibliography	48

EN 16616:2022 (E)**European foreword**

This document (EN 16616:2022) 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 February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

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 16616:2015.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other tests of CEN/TC 216 existing or in preparation and to improve the readability of the document and thereby make it more understandable. The following is a list of significant technical changes since the last edition, EN 16616:2015:

- the scope is adapted to the scope of the WG 1;
- in Clause 4 the requirements for phase 2, step 1 tests are deleted;
- addition of water for the test and reference control (5.2.2.4);
- the example for washing machines in 5.3.2.18 of the previous version is switched to Annex D;
- addition of Potter S 1 apparatus (5.3.2.22);
- adaption of 5.4.3.1 to 5.4.3.3 to other current standards;
- review of 5.4.4 (editorial changes and better description);
- re-wording of the description of the neutralization (5.5.1.2) and addition of a reference to phase 2, step 1 tests;
- addition of an information on using a spectrophotometer for counting cell numbers of mycobacteria in 5.4.4.3 (NOTE);
- addition of the documentation and justification of the choice of the neutralizer in the test report (5.5.1.2);
- addition of a new NOTE in 5.5.2.1;
- addition of a NOTE and the reference to Annex G in 5.5.2.2;
- addition of the reference control (5.5.2.3);
- RII is deleted;
- a reference to phase 2, step 1 tests was added;
- correction and adaption to the current tests of Table 2 (5.6.1.1);

- addition of two paragraphs in 5.6.2.1 (former 5.6.2.3);
- in 5.6.2.2 the V_C -values will be expressed per carrier (former per ml);
- addition of N and N_0 in the calculation (5.6.2.3);
- in 5.6.2.4 the calculation is changed to values per carrier, the formula is corrected and the weighted mean is added in all calculations;
- in 5.6.2.5 calculation is changed: only N_w will be calculated, RI is not counted and RII , B and C are no longer used in the standard;
- correction of the example in 5.7.2;
- adaption of 5.7.3 to the tests in the current version;
- addition of the requirements of the test report in 5.10;
- adaption of Annex A to EN 12353;
- correction of Annex C;
- addition of a new Annex D “Example of washing machine specification”;
- addition of a new Annex E “Preparation of hard water for using in the test and reference procedures”;
- addition of a new Annex F “Test report (example)”;
- addition of a new Annex G “Example for loading the washing machine”;
- document editorially revised, clauses not applied (from the old version) deleted;
- de-harmonization of the standard, Annex ZA deleted.

The changes of this revision have no impact on the test results obtained with reference to the version EN 16616:2015. Those results are still valid except the reduction of the reference control N_w was higher than 3 lg and/or the calculation of the results followed the wrong way of version 2015.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

EN 16616:2022 (E)**Introduction**

This document specifies a carrier test for establishing whether a single-wash disinfecting product or combination of products for the treatment of contaminated textile has or does not have necessary microbicidal activity. This document only intends to validate the disinfection part of the laundry process.

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 could influence its action in practice.

The conditions are intended to cover general purposes and to allow reference between microbiological laboratories and types of detergents and disinfectants. Each effective dosage of the chemical disinfectant found by this test corresponds only to the chosen experimental conditions. Where actual conditions vary additional testing in microbiological laboratories is needed to determine the effective dosage. Instructions for use are the responsibility of manufactures of detergents or disinfectants.

1 Scope

This document specifies a test method and the minimum requirements for the microbicidal activity of a specified disinfection process for the treatment of contaminated textile. This procedure is carried out by using a washing machine as specified in 5.3.2.18 and refers to the disinfection step without prewash. This procedure is not limited to certain types of textile. The suppliers' instructions are expected to be sufficient if they content the process parameters identified in the test (e.g. dosing disinfectant in whatever washing phase e.g. main wash, rinsing, disinfecting at 40 °C).

This document applies to 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 could occur in the workplace and in the home.

It could also include services such as laundries and kitchens supplying products directly for the patients.

The method described is intended to determine the activity of a product or product combination under the conditions in which they are used. This is a phase 2, step 2 laboratory test that simulates the conditions of application of the product.

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

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 13624, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)*

EN 13727, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)*

EN 14348, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)*

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN