

# SVENSK STANDARD

## SS-EN 16616:2015

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### **Kemiska desinfektions- och antiseptiska medel – Kemisk- termisk textil desinfektion – Provningsmetoder och krav (fas 2, steg 2)**

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

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EUROPEAN STANDARD

**EN 16616**

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2015

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ICS 11.080.20

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)

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

This European Standard was approved by CEN on 3 July 2015.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## **European foreword**

This document (EN 16616:2015) 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of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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## **SS-EN 16616:2015 (E)**

### **Introduction**

This European Standard 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. The standard 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 may 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 shall be needed to determine the effective dosage. Instructions for use are the responsibility of manufactures of detergents or disinfectants.



## 1 Scope

This European Standard specifies a test method and the minimum requirements for the microbicidal activity of a defined disinfection process for the treatment of contaminated textile. This procedure is carried out by using a washing machine as defined 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 shall be sufficient to allow the method in the standard to be carried out fully (e.g. dosing disinfectant in whatever washing phase e.g. rinsing, disinfecting at 40 °C).

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

- in hospitals, in community medical facilities and in dental institutions;
- in schools, kindergartens and nursing homes;
- institutions where patients are accommodated, which could suffer from transmissible diseases;
- other applications where hygienic treatment of textile is necessary (e.g. food processing, hotels, workwear e.g. from the pharmaceutical industry, laboratories, foodstuffs area or similar institutions).

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.

NOTE This method corresponds to a phase 2, step 2 test (see EN 14885).

## 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 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*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 and the following apply.

## SS-EN 16616:2015 (E)

### 3.1

#### liquor ratio

ratio of the weight of dry textile in kilogram and volume of wash liquor in litre (w/v)

### 3.2

#### disinfection process

process taking into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances to disinfect the textile

### 3.3

#### treatment of contaminated textile

handling the textile according the disinfection process to obtain disinfected textile

## 4 Requirements

The test results shall fulfil the basic limits (see 5.7.3).

The following phase 2, step 1 test shall be passed in addition to this test: EN 13727, EN 13624 and EN 14348 under the following test conditions:

- temperature as recommended by the manufacturer;
- contact time recommended by the manufacturer;
- dirty conditions and
- reduction as recommended for instrument disinfection.

For products used > 60 °C EN 13624 and EN 14348 should be passed with *Aspergillus brasiliensis* and *M. avium*.

#### a) Processes with temperatures < 60°C

A chemical-thermal textile disinfection process, when tested in accordance with Clause 5, is considered effective when in three test runs (within a given time, with a suggested dosage, at a suggested temperature and liquor ratio) a reduction of bacteria in and on germ carriers of more than 7 log-units, a reduction of *Candida albicans* and *Aspergillus brasiliensis* of 6 lg-units, a reduction of mycobacteria (*M. avium* and/or *M. terrae*) of 7 lg-units is reached.

NOTE The implementation of spores and viruses was discussed. Further development is necessary to make it technically feasible.

Further, no test organisms are to be detected in 100 ml washing/disinfection liquid.

As a minimum requirement the bactericidal and yeasticidal activity shall be evaluated using the following test organisms: for bactericidal activity *Pseudomonas aeruginosa*, *Escherichia coli* (K12), *Staphylococcus aureus*, *Enterococcus hirae* and for yeasticidal activity *Candida albicans* as test organism.

If an additional fungicidal activity is claimed, also *Aspergillus brasiliensis* shall be used as test organism.

In case of an additional proof of tuberculocidal activity, *Mycobacterium terrae* is to be tested.

If a mycobactericidal effect should be confirmed, it is necessary to perform the test also with *Mycobacterium terrae* and *Mycobacterium avium*.

b) Processes with temperatures  $\geq 60^{\circ}\text{C}$ 

A chemical-thermal textile disinfection process, when tested in accordance with Clause 5, is considered as effective when in three test runs (within a given time, with a suggested dosage, at a process temperature  $\geq 60^{\circ}\text{C}$  and a defined liquor ratio) a reduction of *Enterococcus faecium* in and on germ carriers of more than 7 lg-units will be achieved.

Further, no test organisms are to be detected in 100 ml washing/disinfection liquid. This includes fungicidal, mycobactericidal / tuberculocidal activity.

## 5 Test methods

### 5.1 Principle

Germ carriers made of cotton fabric are contaminated with a test suspension of microorganisms in defibrinated sheep blood. After drying the carriers are transferred into cotton bags and then the disinfection process in the washing machine is performed at test temperatures either  $t < 60^{\circ}\text{C}$  or  $\geq 60^{\circ}\text{C}$ . The process refers to the disinfection step without prewash. At the end of the disinfection step of the procedure, the bags with the carriers have to be taken out (see 5.3.2.18). Each carrier is transferred into a separate tube containing neutralizer and glass-beads. The bacteria should be recovered from the carriers by shaking. The number of surviving bacteria in each sample is determined and the reduction rate is calculated.

### 5.2 Materials and reagents

#### 5.2.1 Test organisms

The bactericidal activity shall be evaluated using the following strains as test organisms<sup>1)</sup>

- *Pseudomonas aeruginosa* ATCC 15442
- *Escherichia coli* (K12) ATCC 10538
- *Staphylococcus aureus* ATCC 6538
- *Enterococcus hirae* ATCC 10541
- *Enterococcus faecium* ATCC 6057

The yeasticidal/fungicidal activity shall be evaluated using the following test organisms:

- *Candida albicans* ATCC 10231
- *Aspergillus brasiliensis* ATCC 16404  
(formerly *Aspergillus Niger* ATCC 16404)

The mycobactericidal/tuberculocidal activity shall be evaluated using the following test organisms:

- *Mycobacterium avium* ATCC 15769
- *Mycobacterium terrae* ATCC 15755

NOTE See Annex A for strain reference in some other culture collections.

<sup>1)</sup> The ATCC numbers are the collection numbers of strains supplied by the American Type Culture Collections (ATCC). 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.