SLOVENSKI STANDARD
SIST EN 17658:2023

01-april-2023

Kemična razkužila in antiseptiki - Kemično razkuževanje tekstila za domačo uporabo - Preskusne metode in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Chemical textile disinfection for the domestic area - Test method and requirements (phase 2, step 2)

Chemische Desinfektionsmittel und Antiseptika - Chemische Textildesinfektion für den häuslichen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

Antiseptiques et désinfectants chimiques - Désinfection chimique du textile pour le domaine domestique - Méthode d'essai et prescriptions (phase 2, étape 2)

Ta slovenski standard je istoveten z: **EN 17658:2022**

ICS:

71.100.35	Kemikalije za dezinfekcijo v industriji in doma	Chemicals for industrial and domestic disinfection purposes

SIST EN 17658:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 17658

September 2022

ICS 71.100.35

English Version

Chemical disinfectants and antiseptics - Chemical textile disinfection for the domestic area - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Désinfection chimique du textile pour le domaine domestique - Méthode d'essai et prescriptions (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika - Chemische Textildesinfektion für den häuslichen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 15 August 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, Türkiye 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

Ref. No. EN 17658:2022 E

Contents

Page

European foreword

This document (EN 17658:2022) 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 March 2023, and conflicting national standards shall be withdrawn at the latest by March 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.

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, Türkiye and the United Kingdom.

Introduction

In the last few years, the need of energy saving has led to decreasing washing temperature of domestic laundry to ≤ 40 °C. This fact compromises the level of microorganisms in the laundry items after the washing process. Moreover, the fashion trends on textile design and fibre technology provides cloth items that need to be washed in special care conditions (cool water, short cycles, soft chemistry) in order to preserve their properties but at the same time without compromising their hygienic level.

Chemistry plays an important role to provide good hygienic conditions to domestic laundry under such described conditions.

This document is a phase 2 step 2 test, specifies a lab-scale methodology for establishing if a chemical product used in any of the domestic laundry procedures (main wash and rinse cycle) have a microbicidal activity (bactericidal and yeasticidal activity) on contaminated textiles, washing bath and, an effect in avoiding cross contamination of microorganisms from contaminated textiles to non-contaminated textiles.

This lab-scale methodology is carried out by using a tumbling device able to rotate an exposure chamber 360° around a horizontal axis (Rotawash, Launderometer, Gyrowash, Linitester and Mathis BFA have been validated in the Ring Trial). This tumbling device maintains optimal agitation [constant 40 r/min (±2 r/min)] and precise temperature for consistently reliable test results.

Microorganisms are inoculated on textile carriers that are introduced in an exposure chamber to simulate practical conditions including contact time, temperature, test organisms and interfering substance (conditions which may influence the action of the product in practice). The manufacturer's instructions should be sufficient to allow the method in this document to be carried out fully [dosing, washing phase (main wash, rinse cycle) temperature and washing time].

This test pretends to generate a common experimental framework in which products can be tested to specify their effective dosage for each chosen experimental condition. Instructions for use generated from the results of this test are the responsibility of manufacturers of products.

1 Scope

This document specifies a test method and the minimum performance requirements for the microbicidal efficacy of a chemical product intended for use in a wash process in a domestic environment, in a domestic wash equipment at low temperatures (≤40 °C). This procedure does not apply to certain types of laundry disinfection technologies which require specific devices (i.e. active substances generated *in situ* using specific devices). This method is not limited to certain types of textiles, types of products or steps in the washing cycle.

According to a phase 2, step 2 test definition, this document establishes the efficacy in laboratory test simulating practical use conditions of a chemical product.

This document cannot be applied when the disinfection is medical indicated (medical area) or in hygiene-sensitive areas where professional reprocessing of laundry is required (i.e. food, healthcare, medical and cleanroom sectors, PPE, and workwear). In those cases, EN 16616 and EN 14065 will apply.

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

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 1276, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 1650, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

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 14885:2022, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
liquor ratio
ratio of the weight of dry textile in kilogram and volume of wash liquor expressed 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 to the disinfection process to obtain disinfected textile

3.4
domestic laundry disinfection
treatment of textile (e.g., clothing, kitchen cloths, bed sheet, tablecloth…) with chemical products to inactivate microbial load, the purpose of this level of disinfection being to prevent the transmission of laundry microbiota (cloth, washing machine, wash water) between contaminated and non-contaminated textiles

3.5
biocidal treatment to avoid malodour and aesthetic damage caused by microorganisms
reducing the microorganisms to a level that prevents negative impact to the laundry; damage to aesthetics (e.g., spotting, discolouration, staining) or accumulation of microbial contamination causing mal odour

4 Requirements

The product shall demonstrate at least the following lg reduction when tested in accordance with Table 1 and fulfil the basic limits in 5.7.3.

a) Main wash

1) Domestic laundry disinfection

at least a reduction of bacteria on contaminated carriers of 4 lg, and a reduction of *Candida albicans* of 3 lg. If an additionally fungicidal activity is claimed a reduction of 3 lg shall be reached. Further, no more than 1,54 lg/carrier are to be detected in cross contamination carriers, and no more than 1,15 lg/ml in wash water.

2) Biocidal treatment to avoid malodour and aesthetic damage caused by microorganisms

at least a reduction of bacteria on contaminated carriers of 3 lg, and a reduction of *Candida albicans* of 3 lg. If an additionally fungicidal activity is claimed a reduction of 3 lg shall be reached. Further, no more than 1,70 lg/carrier are to be detected in cross contamination carriers, and no more than 2 lg/ml in wash water.

b) Rinse cycle

1) Domestic laundry disinfection

at least a reduction of bacteria on contaminated carriers of 3 lg, and a reduction of *Candida albicans* of 3 lg. If an additionally fungicidal activity is claimed a reduction of 3 lg shall be

reached. Further, no more than 1,54 lg/carrier are to be detected in cross contamination carriers, and no more than 1,15 lg/ml in wash water.

2) Biocidal treatment to avoid malodour and aesthetic damage caused by microorganisms

at least a reduction of bacteria on contaminated carriers of 2 lg, and a reduction of *Candida albicans* of 2 lg. If an additionally fungicidal activity is claimed a reduction of 2 lg shall be reached. Further, no more than 1,70 lg/carrier are to be detected in cross contamination carriers, and no more than 2 lg/ml in wash water.

Table 1 — Minimum and additional test conditions

Test parameters	**Domestic laundry disinfection**		**Biocidal treatment to avoid malodour and aesthetic damage caused by microorganisms**	
	Main wash	**Rinse cycle**	**Main wash**	**Rinse cycle**
Test organisms	*Escherichia coli, Enterococcus hirae, Pseudomans aeruginosa, Staphylococcus aureus,* *Candida albicans*		*E. coli, E. hirae, P. aeruginosa, S. aureus,* *C. albicans*	
Additionally	Additional test organism(s): - Dermatophytes [a]		Additional test organism(s): - Dermatophytes [a] - Organisms associated with malodour [b]	
Test temperature	As recommended by the manufacturer and ≤ 40 °C [c]	As recommended by the manufacturer and ≤ 20 °C [c]	As recommended by the manufacturer and ≤ 40 °C [c]	As recommended by the manufacturer and ≤ 20 °C [c]
Contact time	As recommended by the manufacturer [c]	As recommended by the manufacturer [c]	As recommended by the manufacturer [c]	As recommended by the manufacturer [c]
Soiling	Dirty: 3,5 g textile SBL2004 (100g ballast fabric)	Clean: BSA in embedding matrix	Dirty: 3,5 g textile SBL2004 (100g ballast fabric)	Clean: BSA in embedding matrix
Liquor ratio	Between 1:2 and 1:10 To specify by the manufacturer	Between 1:2 and 1:10 To specify by the manufacturer	Between 1:2 and 1:10 To specify by the manufacturer	Between 1:2 and 1:10 To specify by the manufacturer

[a] See Annex A for example of dermatophytes. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN.

[b] See Annex A for examples of microorganisms related with malodour. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN.

[c] The temperature and the contact time shall be chosen on the basis of the practical conditions of the product application and within the responsibility of the manufacturer.

5 Test method

5.1 Principle

Textile carriers made of cotton fabric (5.3.2.18) will be contaminated with test suspension of microorganisms in BSA (bovine serum albumin). After drying the carriers will be placed in a tumbling lab testing device containing textile ballast load in which the domestic disinfection process is simulated. Main wash cycle and/or rinse cycle can be simulated. At the end of the disinfection step, the product effect will be stopped by transferring the carriers into neutralizer solution (5.2.2.7) and by shaking at 1 000 r/min in a mixer (5.3.2.6) to extract the remaining microorganisms from the carriers. The amount of recovered microorganisms will be determined and the reduction rate will be calculated compared to an untreated control. In addition, the transfer rate to uninoculated carriers and contamination of the wash liquor will be determined as well.

5.2 Materials and reagents

5.2.1 Test organisms

The bactericidal activity shall be evaluated using the following strains as test organisms[1]

Pseudomonas aeruginosa	ATCC 15442
Escherichia coli	ATCC 10536
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	ATCC 10541

The yeasticidal activity shall be evaluated using the following test organism:

Candida albicans	ATCC 10231

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

The required incubation temperatures for these test organisms are (36 ± 1) °C or (37 ± 1) °C (5.3.2.3) [*C. albicans* (30 ± 1) °C]. The same temperature shall be used for all incubations performed during a test and its controls and validation.

If additional test organisms are used, they shall be incubated under optimum growth conditions (temperature, time, atmosphere, and media) noted in the test report. If the additional test organisms selected do not correspond to the specified strains/species, their suitability for supplying the required inocula shall be verified. If these additional test organisms are not classified at a reference centre, their identification characteristics shall be stated. In addition, they shall be held by the testing laboratory or national culture collection stored under a reference for five years.

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this document refer to the anhydrous salts. Hydrated forms may be used as an alternative, but the weights required shall be adjusted to allow for consequent molecular weight differences.

The reagents shall be of analytical grade and/or appropriate for microbiological purposes. They shall be free from substances that are toxic or inhibitory to the growth of test organisms.

[1] The ATCC numbers are the collection numbers of strains supplied by the American Type Culture Collection (ATCC). This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of the product named.

To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed.

For each culture medium and reagent, a limitation for use should be fixed.

5.2.2.2 Water used for preparation of media

The water shall be fresh distilled water and not just demineralized water. Sterilize in the autoclave (5.3.2.1 a)).

NOTE 1 Sterilization is not necessary if the water is used e.g. for preparation of culture media and subsequently sterilized.

NOTE 2 If distilled water of adequate quality is not available, water for injections (according to European Pharmacopoeia) [1]) can be used.

5.2.2.3 Water of standardized hardness

For the preparation of 1 l of hard water, the procedure is as follows:

— Prepare solution A: Dissolve 19,84 g magnesium chloride ($MgCl_2$) and 46,24 g calcium chloride ($CaCl_2$) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.7) or in the autoclave [(5.3.2.1 a)]. Autoclaving – if used – may cause a loss of liquid. In this case make up to 1 000 ml with water (5.2.2.2) under aseptic conditions. Store the solution in the refrigerator (5.3.2.8) at (2 to 8) °C for no longer than one month.

— Prepare solution B: Dissolve 35,02 g sodium bicarbonate ($NaHCO_3$) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.7). Store the solution in the refrigerator (5.3.2.8) at (2 to 8) °C for no longer than one week.

— Place 600 ml to 700 ml of water (5.2.2.2) in a 1 000 ml volumetric flask (5.3.2.12) and add with the use of a pipette (5.3.2.9) 6,0 ml of solution A, then 8,0 ml of solution B. Mix and dilute to 1 000 ml with water (5.2.2.2). The pH of the hard water shall be 7,0 ± 0,2, when measured at (20 ± 1) °C (5.3.2.4). If necessary, adjust the pH by using a solution of approximately 40 g/l (about 1 mol/l) of sodium hydroxide (NaOH) or approximately 36,5 g/l (about 1 mol/l) of hydrochloric acid (HCl).

The hard water shall be freshly prepared under aseptic conditions and used within 12 h.

5.2.2.4 Tryptone Soy Agar (TSA)

Tryptone, pancreatic digest of casein	15,0 g
Soy peptone, papaic digest of soybean meal	5,0 g
Sodium chloride (NaCl)	5,0 g
Agar	15,0 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization the pH of the medium shall be equivalent to 7,2 ± 0,2 when measured at (20 ± 1) °C.

In case of encountering problems with neutralization (5.5.1.2 and 5.5.1.3) it may be necessary to add neutralizer to the TSA. Annex B gives guidance on the neutralizers that may be used.

5.2.2.5 Malt Extract Agar (MEA)

Malt extract	30,0 g
Agar	15,0 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization the pH of the medium shall be equivalent to 5,6 ± 0,2 when measured at (20 ± 1) °C.

5.2.2.6 Diluent

Tryptone, pancreatic digest of casein	1,0 g
Sodium chloride (NaCl)	8,5 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilize in the autoclave [5.3.2.1 a)]. After sterilization, the pH of the diluent shall be equivalent to 7,0 ± 0,2 when measured at (20 ± 1) °C.

5.2.2.7 Neutralizer

Information on neutralizers that have been found to be suitable for some categories of products is given in Annex B.

5.2.2.8 Interfering substance

5.2.2.8.1 Clean conditions

Prepare test suspensions with a 3 g/l BSA solution.

5.2.2.8.2 Dirty conditions

Prepare test suspensions with a 3 g/l BSA solution.

For main wash conditions 3,5 g SBL2004 (SBL 2004, wfk Testgewebe, Brüggen, Germany) swatches containing approx. 1,2 g standard soil (WFK item number 2814003) will be needed for each test canister. For SBL2004 composition see Annex F.

5.3 Apparatus and glassware

5.3.1 General

Sterilize all glassware and parts of the apparatus that will come into contact with the culture media and reagents or the sample, except those which are supplied sterile, by one of the following methods:

a) by moist heat, in the autoclave [5.3.2.1 a)];

b) by dry heat, in the hot air oven [5.3.2.1 b)].

5.3.2 Usual microbiological laboratory equipment[2]

and, in particular, the following:

[2] Disposable sterile equipment is an acceptable alternative to reusable glassware.

5.3.2.1 Apparatus for sterilization (moist and dry heat)

a) for moist heat sterilization, an autoclave capable of being maintained at (121_{0}^{+3}) °C for a minimum contact time of 15 min [2];

b) for dry heat sterilization, a hot air oven capable of being maintained at (180_{0}^{+5}) °C for a minimum contact time of 30 min, at (170_{0}^{+5}) °C for a minimum contact time of 1 h or at (160_{0}^{+5}) °C for a minimum contact time of 2 h.

5.3.2.2 Water baths, capable of being controlled between (20 ± 1) °C, and (45 ± 1) °C.

5.3.2.3 Incubator, capable of being controlled either at (36 ± 1) °C or (37 ± 1) °C for bactericidal activity, and (30 ± 1) °C for yeasticidal activity. The same temperature shall be used for incubations performed during a test and its controls and validation.

5.3.2.4 pH-meter, having an inaccuracy of calibration of no more than ± 0,1 pH units at (20 ± 1) °C.

A puncture electrode or a flat membrane electrode should be used for measuring the pH of the agar media (5.2.2.4 to 5.2.2.5).

5.3.2.5 Stopwatch

5.3.2.6 Shakers

a) Electromechanical agitator, e.g. vortex mixer;

b) mixer (at 1 000 r/min).

5.3.2.7 Membrane filtration apparatus, constructed of a material compatible with the substances to be filtered, with a filter holder of at least 50 ml volume, and suitable for use of filters of diameter 47 mm to 50 mm and 0,45 µm pore size for sterilization of hard water (5.2.2.3).

5.3.2.8 Refrigerator, capable of being controlled at (2 to 8) °C.

5.3.2.9 Graduated pipettes, of nominal capacities 10 ml, 1 ml, 0,1 ml, and 0,01 ml or calibrated automatic pipettes.

5.3.2.10 Sterile syringes, of nominal capacities 90 ml, and 10 ml.

5.3.2.11 Petri dishes, (plates) of size 90 mm to 100 mm.

5.3.2.12 Volumetric flasks

5.3.2.13 Centrifuge (4 700 *g*).

5.3.2.14 Coned bottom screw cap tubes (contents of 50 ml, diameter: about 28 mm).

5.3.2.15 Polypropylene micro tubes (contents 2 ml) for recovery of the test organisms from the carriers.

5.3.2.16 Stainless steel sieve (the holes shall be smaller than 1 cm × 1 cm).

5.3.2.17 Metal beads (0,9 g approx.; 0,6 cm approx.).

5.3.2.18 Cotton carriers, 1 cm^2 (i.e. wfk 10 A, wfk Testgewebe, Brüggen, Germany): The carriers are prepared by using standard cotton fabric thoroughly cut into 1 cm^2 pieces, cooked in double-distilled water three times and sterilized in the autoclave [see 5.3.2.1 a)].

Mass per unit area:	(170 ± 10) g/m^2 (real 160 g/m^2)
Fibrous material (warp and weft):	cotton, double corded
Fibre length (warp and weft):	at least 27 mm
Yarn linear density (warp and weft):	(295 ± 10) dtex
Yarn twist (warp and weft):	Z-twist (700 ± 25) t/m
Weave:	plain weave 1
Threads per unit length:	270 threads/dm each

The cotton control cloth shall be bleached, unfinished and not brightened.

After three washes the maximum tensile strength, wet, in the warp should be (63 ± 5) daN.

NOTE Cotton proofed in accordance with DIN ISO 2267 [3] fulfils the requirements.

5.3.2.19 Carriers staining

In order to recognize which microorganism has been inoculated in each carrier, each carrier shall be stained with a different colour.

It shall be validated that the dye used is not toxic for any of the microorganisms to be tested.

Stainers validated for this purpose:

a) Marabu textile markers;

b) Simplicol textile dye intensive;

c) Iberia tinte.

For further information see Annex G.

5.3.2.20 Ballast load

Textile of polyester/ cotton (65 % polyester / 35 % cotton) shall be used as ballast load (i.e. wfk 20 A, wfk Testgewebe, Brüggen, Germany).

5.3.2.20.1 Main wash cycle

Total amount of ballast load: 96,5 g polyester/ cotton textile in addition to 3,5 g of SBL2004. In case the used lab tumbling testing device uses another exposure chamber of another volume, test volumes and ballast loads indicated below have to be adjusted accordingly.

Cut 96,5 g of ballast fabric in to 10 cm × 10 cm squares. Boil with sterile distilled water two times. Air dry fabric until completely dry. Introduce 96,5 g of ballast into a container or inside the canister and autoclave for 15 min at 121 °C, ensure fabric is completely dry before use.

The ballast load for product testing should not be used more than once. For water control ballast can be reused 3 times before discarding.