SLOVENSKI STANDARD
oSIST prEN 17658:2021

01-april-2021

Kemična razkužila in antiseptiki - Kemična dezinfekcija 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: **prEN 17658**

ICS:

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

oSIST prEN 17658:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT prEN 17658

April 2021

ICS 71.100.35

English Version

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 17658:2021) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

Introduction

Domestic laundry disinfection has taken relevance in the last few years with the new social trends of energy saving based on decreasing the washing temperature of domestic laundry to ≤ 40°C. This fact, together with the social trend of speediness, makes domestic laundry washes to be shorter in time which compromise 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 rinsing) 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 through 360° vertical orbit (Rotawash, Launderometer, Gyrowash, Linitester and Mathis BFA have been validated in the Ring Trial). This tumbling device maintains optimal agitation (constant 40 rpm (±2 rpm)) 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 organism and interfering substance (conditions which may influence the action of the product in practice). The manufacturers instructions should be sufficient to allow the method in this document to be carried out fully (dosing, washing phase (main wash, rinsing) temperature and washing time).

This test pretends to generate a common experimental framework in which products can be tested to define 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 requirements for the microbicidal activity of a chemical product which intended use is the chemical treatment of textiles in domestic area in order to evaluate the hygiene performance of domestic laundry products within domestic washing machines at low temperatures (≤40°C). This procedure will not apply to certain types of laundry disinfection technologies which require specific devices (i.e active substances generated *in situ* through the use of specific devices). This method is not limited to certain types of textiles, types of products or steps in the washing cycle.

This document can also apply to products that are used for chemical disinfection of textiles in food, industrial and institutional areas (e.g. food processing, shops, sport rooms, offices, hotels, workwear, foodstuff areas or similar institutions) but not when the disinfection is medical indicated (medical area).

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, *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 http://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 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

3.4
domestic and non-medical laundry disinfection
treatment of textile (e.g. clothing, kitchen cloths, bed sheet house, 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
aesthetic and malodour treatment
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

   a. Domestic and non-medical laundry disinfection

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

   b. Aesthetic and malodour treatment

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

b) Rinsing cycle

   a. Domestic and non-medical laundry disinfection

      at least a reduction of bacteria on contaminated carriers of more than 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 cfu (lg/carrier) are to be detected in cross contamination carriers, and no more than 1,15 cfu (lg/ml) in wash water.

   b. Aesthetic and malodour treatment

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

Table 1 — Minimum and additional test conditions

Test parameters	Domestic and non-medical laundry disinfection		Aesthetic and malodour treatment	
	Main wash	Rinse cycle	Main wash	Rinse cycle
Test organisms	*E. coli, E. hirae, P. aeruginosa, S. aureus, C. albicans*		*E. coli, E. hirae, P. aeruginosa, S. aureus, C. albicans*	
Additionally	Additional test organism Dermatophytes *T. rubrum* *T. mentagrophytes* *M. canis* Organisms associated with malodour		Additional test organism Dermatophytes *T. rubrum* *T. mentagrophytes* *M. canis* Organisms associated with malodour	
Test temperature	As recommended by the manufacturer and ≤ 40°C[a]	As recommended by the manufacturer and ≤ 20°C[a]	As recommended by the manufacturer and ≤ 40°C[a]	As recommended by the manufacturer and ≤ 20°C[a]
Contact time	As recommended by the manufacturer[a]	As recommended by the manufacturer[a]	As recommended by the manufacturer[a]	As recommended by the manufacturer[a]
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 define by the manufacturer	Between 1:2 and 1:10 To define by the manufacturer	Between 1:2 and 1:10 To define by the manufacturer	Between 1:2 and 1:10 To define by the manufacturer

[a] 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. 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 rinsing cycle can be simulated. At the end of the disinfection step, the product effect will be stopped by transferring the carriers into neutralizer solution (5.2.1.6) and by shaking at 1000 rpm in a thermomixer (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.

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.

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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.

NOTE 2 If distilled water of adequate quality is not available, water for injections (see bibliographic reference [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 (5.2.1.1) 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 (5.2.3.4). 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 (5.2.1.1)	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 0,3 % BSA (Bovine serum albumin) solution.

5.2.2.8.2 Dirty conditions

Prepare test suspensions with a 0,3 % BSA solution.

For main wash conditions add 3,5 g SBL2004 swatches containing approx. 1,2 g standard soil (WFK item number 2814003).

SBL2004 % composition	
Vegatable Oil (Olio Extra Vergine di Oliva)	18 % – 20 %
Synthetic Sebum (BEY)	18 % – 20 %
Kaoline	8 % – 10 %
Proteine (from egg white powder)	8 % – 10 %
Bleach Consuming Agent	8 % – 10 %
Starch (corn starch)	6 % – 8 %
Salt (NaCl)	6 % – 8 %
Mineral Oil	6 % – 8 %
Lanolin	6 % – 8 %
Emulgator (Uniperol ® dispersing agent, BASF)	1 % – 3 %
Urea (synthetic)	1 % – 3 %
Quartz	1 % – 3 %
Calciumchloride	1 % – 3 %
Carbon Black / Soot	< 1 %
Iron Oxide black	< 1 %

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:

5.3.2.1 Apparatus for sterilization (moist and dry heat)

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

b) for dry heat sterilization, a hot air oven capable of being maintained at $(180\,^{+5}_{0})$ °C for a minimum contact time of 30 min, at (170^{+5}_{0})°C for a minimum contact time of 1 h or at $(160\,^{+5}_{0})$ °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 (5.2.2.5 to 5.2.2.9).

5.3.2.5 Stopwatch

5.3.2.6 Shakers

a) Electromechanical agitator, e.g. Vortex® mixer[3)]

b) Thermomixer (at 1000 rpm).

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

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

3) Vortex® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product.