SLOVENSKI STANDARD
SIST EN 13697:2015/oprA1:2018

01-junij-2018

Kemična razkužila in antiseptiki - Kvantitativni preskus na neporoznih površinah za vrednotenje baktericidnega in/ali fungicidnega delovanja kemičnih razkužil v živilski in drugih industrijah, gospodinjstvu in javnih ustanovah - Preskusna metoda in zahteve brez mehanskega delovanja (faza 2, stopnja 2) - Dopolnilo A1

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Oberflächen-Versuch zur Bestimmung der bakteriziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel auf nicht porösen Oberflächen in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren und Anforderungen ohne mechanische Behandlung (Phase 2, Stufe 2); Deutsche und Englische Fassung EN 13697/prA1:2017

Ta slovenski standard je istoveten z: **EN 13697:2015/prA1**

ICS:

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

SIST EN 13697:2015/oprA1:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT EN 13697:2015

prA1

May 2018

ICS 11.080.20; 71.100.35

English Version

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)

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This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 216.

This draft amendment A1, if approved, will modify the European Standard EN 13697:2015. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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.

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Recipients of this draft are invited to submit, with their c[illegible]ation of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (EN 13697:2015/prA1:2018) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is submitted to the CEN Enquiry.

Option 1

Data from the latest EN 13697 are still valid with the exception of:

— Pseudomonas aeruginosa and Candida albicans under clean conditions

or

Option 2

Data from the latest EN 13697 are still valid

(to be discussed during CEN Enquiry).

1 Modification to Clause 4

Replace Table 1 by the following:

Table 1 — Experimental conditions

Test Conditions	**Bactericidal activity on non-porous surfaces without mechanical action**	**Yeasticidal activity on non-porous surfaces without mechanical action**	**Fungicidal activity on non-porous surfaces without mechanical action**
Test organism (see 5.2.1) **minimum spectrum of test organisms**	*Enterococcus hirae* *Escherichia coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	*Candida albicans*	*Candida albicans* *Aspergillus brasiliensis (ex A. niger)*
Test organisms **additional** (examples)	*Salmonella typhimurium* *Lactobacillus brevis* *Enterobacter cloacae*	*Saccharomyces cerevisiae* (for breweries) *Saccharomyces cerevisiae var. diastaticus* (for breweries)	any relevant test organism
Test temperature	In a range from 4 ± 1°C to 40 ± 1°C For tests performed at room temperature, the range shall be between 18°C and 25°C°C	In a range from 4 ± 1°C to 40 ± 1°C For tests performed at room temperature, the range shall be between 18°C and 25°C°C	In a range from 4 ± 1°C to 40 ± 1°C For tests performed at room temperature, the range shall be between 18°C°C and 25°C°C
Contact time	in a range from 1 min and between 5 and 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)	in a range from 1 min and between 5 and 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)	in a range from 1 min and between 5 and 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min)
Interfering substance clean conditions	0,3 g/l Bovine Albumin for *Staphylococcus aureus*, *Enterococcus hirae*, *Escherichia coli* and *Pseudomonas aeruginosa*	0,3 g/l Bovine Albumin for *C. albicans*	0,3 g/l Bovine Albumin for *C. albicans* and *A. brasiliensis*
Interfering substance dirty conditions	3,0 g/l Bovine Albumin for *Staphylococcus aureus*, *Enterococcus hirae*, *Pseudomonas aeruginosa* and *Escherichia coli*	3,0 g/l Bovine Albumin for *C. albicans*	3,0 g/l Bovine Albumin for *C. albicans* and *A. brasiliensis*

Test Conditions	Bactericidal activity on non-porous surfaces without mechanical action	Yeasticidal activity on non-porous surfaces without mechanical action	Fungicidal activity on non-porous surfaces without mechanical action
Interfering substance **additional**	any relevant substance	any relevant substance	any relevant substance
Log reduction from a water control (decimal log)	≥ 4Lg	≥ 3Lg	≥ 3Lg
The referenced test conditions are by no means intended as requirements for the use of a product, nor as requirements for the evaluation and acceptance of products by regulatory authorities. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Where appropriate (specific purposes), additional specific bactericidal/yeasticidal/fungicidal activity shall be determined under other conditions of time, temperature, additional strains and interfering substances in order to take into account intended specific use conditions.			

2 Modification to Clause 5.2.2.8.2

Replace the title of Clause 5.2.2.8.2. as follows

Bovine albumin solutions

Replace the whole text of Clause 5.2.2.8.2 by the following:

Bovine albumin solutions for the test conditions shall be prepared as follows:

— Preparation for clean conditions:

  — dissolve 0,06 g of bovine albumin (Cohn fraction V for Dubos medium) in 100 ml of water (see 5.2.2.2);

  — sterilize by 0,45 µm membrane filtration (see 5.3.2.19), keep in the refrigerator and use within one month.

The final concentration of bovine albumin in the test procedure (see 5.5.2) is 0,3 g/l.

— Preparation for dirty conditions;

  — dissolve 0,60 g of bovine albumin (Cohn fraction V for Dubos medium) in 100 ml of water (see 5.2.2.2);

  — sterilize by 0,45 µm membrane filtration (see 5.3.2.19), keep in the refrigerator and use within one month.

The final concentration of bovine albumin in the test procedure (see 5.5.2) is 3,0 g/l.

In addition, other interfering substances for chemical disinfectants with detergent properties (therefore simulating additional dirty conditions for specific uses) can be chosen:

3 Modification to Clause 5.2.2.8.3

At the end of Clause 5.2.2.8.3, replace

The final concentration of milk in the test procedure (see 5.5.2) shall be 1,0 % (V/V) of reconstituted milk.

with

The final concentration of the reconstituted milk should be 1.0 % (v / v) in the test (see 5.5.2) or 1 g/ L of milk powder during the test.

4 Modification to Clause 5.2.2.8.4

Delete the whole clause.

5 Modification to Clause 5.2.2.8.5

Delete the whole clause.

6 Modification to Clause 5.2.2.8.6

Delete the whole clause.

7 Modification to Clause 5.2.2.9

Delete the whole clause.

8 Modification to Clause 5.3.2.2

Replace the title of clause 5.3.2.2 by the following

Temperature controlled cabinet capable of being controlled at test temperatures, θ ± 1 °C

9 Addition of new Clause 5.3.2.20

Add the following new clause after Clause 5.3.2.19

5.3.2.20 Vacuum desiccator, *Desiccator* with an active desiccant. Vacuum source may be a pump or central supply and should achieve a vacuum of 20-25 in mercury (508- 635 torr; 677-847 mbar; 68000-85000 Pascal; conversion tables are readily available on the Internet for other units).

10 Modification to Clause 5.4.1.3

Replace the text of a) by the following:

a) Bacterial test suspension:

Take 10 ml of diluent (see 5.2.2.5) and place in a 100 ml flask with 5 g of glass beads (see 5.3.2.12). Take the working culture (see 5.4.1.2) and transfer loopfuls of the cells into the diluent. The cells should be suspended in the diluent by immersing the loop in the diluent and rubbing it against the side of the flask to dislodge the cells. Shake the flask for 3 min using a mechanical shaker (see 5.3.2.14). Aspirate the suspension from the glass beads and transfer to another flask. Adjust the number of cells in the suspension to $1{,}5 \times 10^8$ cfu/ml to $5{,}0 \times 10^8$ cfu/ml using the diluent for *S. aureus, Pseudomonas aeruginosa for tests under dirty conditions, E. coli* and *E. hirae*.

Adjust the number of cells in the suspension to 1,5 x 10^9 cfu/ml to 5,0 x 10^9 cfu/ml using the diluent for *P. aeruginosa* for tests to be performed under clean conditions.

The numbers of units shall be estimated by means of spectrophotometer or any other suitable means. Maintain this suspension in the water bath at 20 C ± 1 C and use within 2 h.

Replace the text of b) 1) by the following

1) *Candida albicans*:

Take 10 ml of diluent (see 5.2.2.5) and place in a 100 ml flask with 5 g of glass beads. Take the working culture (see 5.4.1.2) and transfer loopfuls of the cells into the diluent. The cells should be suspended in the diluent by immersing the loop in the diluent and rubbing it against the side of the flask to dislodge the cells. Shake the flask for 3 min using a mechanical shaker (5.3.2.14). Aspirate the suspension from the glass beads and transfer to another flask. Adjust the number of cells in the suspension to 1,5 × 10^8 cfu/ml to 5,0 x 10^8 cfu/ml using the diluent for tests to be performed under clean conditions, estimating the numbers of units by means of a spectrophotometer or other suitable technique. Maintain this suspension in the water bath at 20 °C ± 1 °C and use within 2 h. Adjust the number of cells in the suspension to 1,5 × 10^7 cfu/ml to 5,0 x 10^7 cfu/ml using the diluent for tests to be performed under dirty conditions, estimating the numbers of units by means of a spectrophotometer or other suitable technique. Maintain this suspension in the water bath at 20 °C ± 1 °C and use within 2 h.

11 Modification to Clause 5.4.1.4

Replace the whole text by the following

Dilute the adjusted bacterial and yeast suspensions (see 5.4.1.3) by 10^{-6} (serial dilutions) and 10^{-7} for *S.aureus, E. coli, E. hirae* and *C. albicans*, by 10^{-7} (serial dilutions) and 10^{-8} for *P. aeruginosa* and by 10^{-5} and 10^{-6} for the mould spore suspension (see 5.4.1.3)using diluent (see 5.2.2.5). Mix the suspension (see 5.3.2.8).

Take a sample of 1,0 ml of each dilution in duplicate and inoculate pour plates. Pipette each 1,0 ml sample into separate Petri dishes (see 5.3.2.11) and add 15 ml to 20 ml melted TSA (see 5.2.2.2) for the bacteria and 15 ml to 20 ml melted MEA (see 5.2.2.3) for the fungi, cooled to 45 °C ± 1 °C.

a) Counting of bacterial test suspensions

   1) For the bacterial strains, incubate the plates at 36 °C ± 1 °C or at (37 ± 1) °C for 18-24 h. Discard any plates which are not countable for any reason. Incubate the plates for a further 18-24 h. Do not recount plates which no longer show countable colonies. Recount the remaining plates.

b) Counting of fungal test suspensions

   1) For the fungal strains, incubate the plates at 30 C ± 1 C for 18-24 h (*Candida albicans*), for 42 h to 48 h (*Aspergillus brasiliensis*. Discard any plates which are not countable for any reason. Count the plates and determine the number of colony forming units. Incubate the plates for a further 18-24 h. Do not recount plates which no longer show well-separated colonies. Recount the remaining plates. For *Aspergillus brasiliensis*, continue incubation for a further 20 h to 24 h and if necessary a further 20 h to 24 h, provided the number of countable colonies (discrete colonies) is increasing.

Determine the highest number of colonies for each 1 ml sample.

For incubation and counting, see 5.4.1.5.