SLOVENSKI STANDARD
oSIST prEN 17915:2022

01-december-2022

Kemična razkužila in antiseptiki - Kvantitativna preskusna metoda s steklenim nosilcem za vrednotenje virucidnega delovanja kemičnih razkužil na trdih neporoznih površinah v živilski in drugih industrijah, gospodinjstvu in javnih ustanovah - Preskusna metoda in zahteve (faza 2, stopnja 2)

Chemical disinfectants and antiseptics - Quantitative carrier test method for the evaluation of virucidal activity of chemical disinfectants on hard non-porous surfaces in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 2)

Chemische Desinfektionsmittel und Antiseptika – Quantitative Keimträgerprüfung zur Bestimmung der viruziden Wirkung chemischer Desinfektionsmittel auf harten nicht-porösen Oberflächen in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen – Prüfverfahren und Anforderungen (Phase2, Stufe2)

Antiseptiques et désinfectants chimiques - Essai quantitatif de surface non poreuse sans action mécanique pour l'évaluation de l'activité virucide des désinfectants chimiques utilisés dans l'agroalimentaire, l'industrie, la sphère domestique et les collectivités - Méthode d'essai et exigences (phase 2, étape 2)

Ta slovenski standard je istoveten z: **prEN 17915**

ICS:

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

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EUROPEAN STANDARD

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Chemical disinfectants and antiseptics - Quantitative carrier test method for the evaluation of virucidal activity of chemical disinfectants on hard non-porous surfaces in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 2).

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

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification 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 (prEN 17915:2022) 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

This document describes a surface test method for establishing whether a product proposed as a disinfectant in the fields described in Clause 1 has or does not have virucidal activity on non-porous surfaces.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, organisms on surfaces etc.) reflect parameters which are found in practical situations including conditions which may influence the action of disinfectants. Each use concentration found from this test corresponds to defined experimental conditions.

The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to defined experimental conditions.

However for special applications the recommendations of use of a product can differ and therefore additional test conditions might be needed, which cannot be covered by this European Standard.

1 Scope

This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectants that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products - with water.

This document applies to products that are used in the food, industrial, domestic and institutional area for disinfecting non-porous surfaces without mechanical action, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues.

This document applies at least to the following:

a) processing, distribution and retailing of:

   1) food of animal origin:

      — milk and milk products;

      — meat and meat products;

      — fish, seafood, and related products;

      — eggs and egg products;

      — animal feeds;

      — etc.;

2) food of vegetable origin:

   — beverages;

   — fruits, vegetables and derivatives (including sugar, distillery, etc.);

   — flour, milling and baking;

   — animal feeds;

   — etc.;

b) institutional and domestic areas:

   — catering establishments;

   — public areas;

   — public transports;

   — schools;

   — nurseries;

   — shops;

   — sports rooms;

- waste containers (bins, etc.);
- hotels;
- dwellings;
- clinically non sensitive areas of hospitals;
- offices;
- etc.;

c) industries other than food:

- packaging material;
- biotechnology (yeast, proteins, enzymes, etc.);
- pharmaceutical;
- cosmetics and toiletries;
- textiles;
- space industry, computer industry;
- etc.

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

EN 10088-1, *Stainless steels - Part 1: List of stainless steels*

EN 10088-2, *Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

3 Terms and definitions

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

3.1
cytotoxicity
morphological alteration of cells and/or their destruction or their reduced sensitivity to virus multiplication caused by the product

3.2
plaque forming units
PFU
number of infectious virus particles per unit volume (ml)

3.3
reference test for virus inactivation
test with a defined product (e.g. glutaraldehyde) in parallel with a product under test for the internal control of the test

3.4
$TCID_{50}$
50 % infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE (3.5) in 50 % of cell culture units

3.5
viral cytopathic effect
CPE
morphological alteration of cells and/or their destruction as a consequence of virus multiplication

3.6
viral plaque
area of lysis formed in a cell monolayer under semisolid medium due to infection by and multiplication of a single infectious virus particle

3.7
virus titre
amount of infectious virus per unit volume present in a cell culture lysate or in a solution

3.8
virucidal activity
capability of a product to reduce the number of infectious virus particles of adenovirus and murine norovirus for surfaces disinfection in applications other than food processing, distribution and retailing, and murine norovirus for food processing, distribution and retailing areas

3.9
high level virucidal activity
capability of a product used in healthcare areas and other professional areas where disinfection is medically indicated to reduce the number of infectious virus particles of murine parvovirus for surfaces disinfection in industries other than institutional, domestic, food processing distribution and retailing areas

3.10
virucidal activity against enveloped viruses
capability of a product to reduce the number of infectious virus particles of Vaccinia virus, covering activity against all enveloped viruses

4 Requirements for virucidal activity on surfaces

The product shall demonstrate at least a decimal log (lg) reduction of 4 in virus titre, when tested in accordance with Table 1 and Clause 5.

Table 1 — Minimum and additional test conditions

Minimum conditions	**Surfaces disinfection in industries, food processing, distribution and retailing areas**	**Surfaces disinfection in institutional and domestic areas**
Minimum spectrum of test organisms	**Virucidal activity for biopharmaceutical industry** *Murine Parvovirus* **Virucidal activity for industries other than biopharmaceutical and food industry** *Adenovirus* *Murine Norovirus* **Virucidal activity for food industry** *Murine Norovirus* **Virucidal activity against enveloped viruses** *Vaccinia virus* **Virucidal activity (chemo-thermal)** *Murine Parvovirus for temperatures >40°C*	**Virucidal activity for institutional and domestic use** *Adenovirus* *Murine Norovirus* **Virucidal activity against enveloped viruses** *Vaccinia virus*
Test temperature	between 18 °C and 25 °C but for chemo-thermal activity	between 18°C and 25 °C
Additional temperature	between 4 °C and ≤ 40 °C	between 4 °C and and ≤ 40 °C
Contact time	according to the manufacturer's recommendation, but not longer than 60 min[c]	according to the manufacturer's recommendation, but not longer than 60 min[c]

Minimum conditions	Surfaces disinfection in industries, food processing, distribution and retailing areas	Surfaces disinfection in institutional and domestic areas
Interfering substances a) clean b) dirty	0,3 g/l bovine serum albumin **and/or** 3,0 g/l bovine serum albumin	0,3 g/l bovine serum albumin **and/or** 3,0 g/l bovine serum albumin
Additional conditions[a]	Further contact time(s), interfering substance(s) or virus(es)	Further contact time(s), interfering substance(s) or virus(es)

[a] Where appropriate (specific purposes), additional specific virucidal activity shall be determined under other conditions of time, temperature, and interfering substances (see 5.2.2.8) in accordance with 5.5, in order to take into account intended specific use conditions. Additional virus(es) can be tested, if relevant. For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.

[b] The test for "virucidal activity against enveloped viruses" will cover all enveloped viruses only

[c] The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer.

[d] Adenovirus to be tested only for surface disinfection in applications other than food processing, distribution and retailing

The determined virucidal concentration of the test product is suggested as being suitable for practical situations of use.

5 Test methods

5.1 Principle

5.1.1 A test suspension of viruses in a solution of interfering substances is inoculated onto a test surface and dried. A prepared sample of the product under test is applied in a manner which covers the dried film.

The test surface is maintained at a specified temperature for a defined period of time. The test surface is transferred to cell maintenance medium so that the action of the disinfectant is immediately neutralized. The titre of the virus recovered from the test surface is determined.

The titre of the inoculum on a test surface treated with hard water in place of the disinfectant is also determined and the reduction in virus titre attributed to the product is calculated by difference.

5.1.2 The test is performed using the test organisms as specified in Clause 4, Table 1.

5.1.3 Other contact times and temperatures within the limits specified in Clause 4, Table 1 may be used. Additional interfering substances and test organisms may be used.