SLOVENSKI STANDARD
oSIST prEN 17914:2022

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Kemična razkužila in antiseptiki - Kvantitativna suspenzijska preskusna metoda za vrednotenje virucidnega delovanja kemičnih razkužil in antiseptikov v živilski in drugih industrijah, gospodinjstvu in javnih ustanovah - Preskusna metoda in zahteve (faza 2, stopnja 1)

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

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung chemischer Desinfektionsmittel und Antiseptika in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

Antiseptiques et désinfectants chimiques - Méthode d'essai quantitatif de suspension pour l'évaluation de l'activité virucide des antiseptiques et des désinfectants chimiques dans l'agroalimentaire, l'industrie, la sphère domestique et les collectivités - Méthode d'essai et exigences (phase 2, étape 1)

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

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

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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 17914:2022) 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 specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a virucidal activity in the area and fields described in the scope.

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 practical situations. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.

1 Scope

This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i. e, products that are not diluted when applied – with water. Products can only be tested at a concentration of 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products that are used in the food, industrial, domestic and institutional area for hand disinfection, hygienic hand washing, surface disinfection by wiping, spraying, flooding or otherwise, and for disinfection of textile and equipment, 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:

- food of animal origin:
  - milk and milk products;
  - meat and meat products;
  - fish, seafood, and related products;
  - eggs and egg products;
  - animal feeds;
  - etc.;
- 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.

NOTE 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*

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 for hygienic handrub and handwash, for surfaces disinfection in applications other than food processing, distribution and retailing, murine norovirus for food processing, distribution and retailing areas, and murine parvovirus for uses at a temperature >40°C

3.9
limited spectrum virucidal activity
capability of a product to reduce the number of infectious virus particles of all enveloped viruses (Annex A) and norovirus, rotavirus and adenovirus for hygienic handrub and handwash

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

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

Test Conditions	Hygienic handrub and handwash	Surfaces disinfection in industries, food processing, distribution and retailing areas	Surfaces disinfection in institutional and domestic areas	Disinfection of textile
Minimum spectrum of test organisms	**Limited spectrum virucidal activity** *Adenovirus* *Murine Norovirus* **Virucidal activity against enveloped viruses** *Vaccinia virus*	**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** *Murine Parvovirus for temperatures > 40°C*	**Virucidal activity for institutional and domestic use** *Adenovirus* *Murine Norovirus* **Virucidal activity against enveloped viruses** *Vaccinia virus*	**Virucidal activity for institutional and domestic use** *Adenovirus* *Murine Norovirus* **Virucidal activity against enveloped viruses** *Vaccinia virus* **Virucidal activity** *Murine Parvovirus for temperatures > 40°C*
additional	Any relevant test organism			
Test temperature	according to the manufacturer's recommendation, but at / between			
	20 °C	4 °C and ≤ 40 °C	4 °C and ≤ 40 °C	10°C and 70°C for main wash cycle 10°C and 20°C for rinse cycle
Contact time	according to the manufacturer's recommendation			
	but between 30 s and 60 s 30 s and 120s[e] for high level virucidal activity	60 min	but no longer than 60 min	but no longer than 60 min for wash cycle 20 min for rinse cycle

Test Conditions	Hygienic handrub and handwash	Surfaces disinfection in industries, food processing, distribution and retailing areas	Surfaces disinfection in institutional and domestic areas	Disinfection of textile
Interfering substance				
clean conditions	0,3 g/l bovine albumin solution (hygienic handrub)	0,3 g/l bovine albumin solution **and/or**	0,3 g/l bovine albumin solution **and/or**	0,3 g/l bovine albumin solution (rinse cycle) 3,0 g/l bovine albumin solution (wash cycle)
dirty conditions	3,0 g/l bovine albumin solution (hygienic handwash)	3,0 g/l bovine albumin solution	3,0 g/l bovine albumin solution	
Additional conditions	clean or dirty; any relevant substance	any relevant substance	any relevant substance	any relevant substance

5 Test methods

5.1 Principle

5.1.1 A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of viruses in a solution of an interfering substance. The mixture is maintained at one of the temperatures and the contact times specified in Clause 4, Table 1 and 5.5.1.1. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilution of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units (petri dishes, tubes or wells of microtitre plates) either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Kärber (quantal tests, C.1) or by plaque counting (plaque test, C.2) and evaluated. Reduction of virus infectivity is calculated from differences of lg virus titres before (virus control) and after treatment with the product.

NOTE Handwash products are always prediluted with hard water (5.2.2.7) and the resulting solution is regarded as a ready-to-use product (5.4.2).

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.