

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

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 13610:2003 sisaldab Euroopa standardi EN 13610:2002 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.02.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 13610:2003 consists of the English text of the European standard EN 13610:2002.</p> <p>This document is endorsed on 18.02.2003 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p>Käsitlusala: This European Standard specifies a test method (phase 2, step 1) and requirements for the minimum virucidal activity against bacteriophages of chemical disinfectants that form a homogeneous, physically stable preparation in hard water and that are used in food and industrial areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues</p>	<p>Scope: This European Standard specifies a test method (phase 2, step 1) and requirements for the minimum virucidal activity against bacteriophages of chemical disinfectants that form a homogeneous, physically stable preparation in hard water and that are used in food and industrial areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues</p>
--	--

ICS 11.080.20, 67.050, 71.100.35

Võtmesõnad: bactericides, disinfection, flours, food, food products, fruits, hygiene, industries, meat, meat product, milk, quantitative analysis, specification (approval), specifications, suspension tests, suspensions (chemical), testing, vegetables

ICS 11.080.20; 67.050; 71.100.35

English version

Chemical disinfectants

Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas

Test method and requirements (phase 2, step 1)

Désinfectants chimiques – Essai quantitatif de suspension pour l'évaluation de l'activité virucide contre les bactériophages des désinfectants chimiques utilisés dans le domaine de l'agro-alimentaire et dans l'industrie – Méthode d'essai et exigences (phase 2, étape 1)

Chemische Desinfektionsmittel – Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung gegenüber Bakteriophagen von chemischen Desinfektionsmitteln in den Bereichen Lebensmittel und Industrie – Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 2002-10-23.

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 Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Contents

	Page
Foreword.....	3
Introduction.....	3
1 Scope	4
2 Normative references	5
3 Terms and definitions	5
4 Requirements	6
5 Test methods	6
5.1 Principle	6
5.2 Material and reagents	6
5.3 Apparatus and glassware	11
5.4 Preparation of host bacteria suspensions	12
5.5 Preparation of bacteriophage suspension	13
5.6 Product test solution	15
5.7 Procedure	15
5.8 Calculation and expression of results	18
5.9 Test report	22
Annex A (normative) Test for validation of dilution-neutralization and molecular sieving methods	24
Annex B (informative) Neutralizers	32
Annex C (informative) Example of a typical test report	34
Annex D (informative) Information on the application and interpretation of European standards on chemical disinfectants and antiseptics	38
Annex E (informative) Example of plaques from lysates of phages P001 and P008	40
Bibliography	42

Preview generated by EVS

Foreword

This document (EN 13610:2002) has been prepared by Technical Committee CEN /TC 216, "Antiseptics and chemical disinfectants" 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 June 2003, and conflicting national standards shall be withdrawn at the latest by June 2003.

In this European Standard the Annex A is normative and the Annexes B, C, D and E are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard describes a suspension test method intended to establish whether a product proposed as a disinfectant in the fields described in clause 1 has or does not have virucidal activity against bacteriophages.

NOTE Virulent bacteriophages (phages) lytic for (i.e. virulent for) starter cultures of *Lactococcus lactis* subsp. *lactis* used for the production of cheese and other fermented milk products are used as model viruses to test the virucidal activity of a product.

The laboratory test closely simulates practical conditions of application. Chosen conditions (contact time, temperature, viruses [i.e. bacteriophages] in suspension, ...) reflect parameters which are found in practical situations including conditions which may influence the action of disinfectants.

Each utilization 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.

However for some applications the recommendations of use may differ and therefore additional test conditions need to be used.

1 Scope

This European Standard specifies a test method (phase 2, step 1) and requirements for the minimum virucidal activity against bacteriophages of chemical disinfectants that form a homogeneous, physically stable preparation in hard water and that are used in food and industrial areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues.

This European Standard 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 their products;
- eggs and egg products;
- animal feeds;
- etc.;

2) food of vegetable origin:

- beverages;
- fruits, vegetables and their derivatives (including sugar, distillery ...);
- flour, milling and baking;
- animal feeds;
-;

b) other industrial areas:

- biotechnology (yeast, proteins, enzymes, ...).

Using this European Standard, it is not possible to determine the virucidal activity against bacteriophages of undiluted product as some dilution is always produced by adding the inoculum and interfering substance.

For chemical disinfectants that can be used without dilution it is not possible to determine whether these products, at a concentration above 80 % have a virucidal activity against bacteriophages.

NOTE The method described is intended to determine the activity of commercial formulations or active substances on viruses (bacteriophages) in the conditions in which they are used.

This European Standard is applicable only to disinfectants, complying with the validation test (see annex A).

2 Normative references

Not applicable.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1

product (for chemical disinfection and/or antiseptis)

chemical agent or formulation used as a chemical disinfectant or antiseptic

[EN 1040:1997]

3.2

virucide against bacteriophages

product which inactivates the bacteriophages

NOTE The adjective derived from "virucide" is "virucidal".

3.3

virucidal activity against bacteriophages

capability of a product to reduce the infectivity of intact bacteriophages belonging to reference bacteriophage strains P001 and P008 for at least 4 lg under the conditions defined by this standard

3.4

infectivity of bacteriophages

the ability of a bacteriophage to propagate in a suitable host bacterial cell resulting in the release of bacteriophage progeny

3.5

inactivation of bacteriophage

the reduction of infectivity of a bacteriophage by a product specified as a chemical disinfectant

3.6

reference bacteriophage suspension

bacteriophage suspension of a defined virus strain maintained in reference centers and which should not be passaged more than 10 times

3.7

stock bacteriophage suspension

bacteriophage suspension of a defined strain that has been multiplied on a large scale to obtain a bacteriophage suspension revealing identical characteristics as the reference bacteriophage suspension

NOTE This stock bacteriophage suspension is used to prepare a high-titer test bacteriophage suspension for the bacteriophage inactivation test.

3.8

high-titer bacteriophage suspension

the high-titer bacteriophages suspension obtained from agar plates revealing confluent lysis in the bacterial lawn that is used to prepare the bacteriophage test suspension in the virucidal testing of the disinfectant

3.9

bacteriophage test suspension

the bacteriophage suspension of a defined titer that is used in the virucidal testing of the disinfectant