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English Version

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Antiseptiques et désinfectants chimiques - Application des Normes européennes sur les antiseptiques et désinfectants chimiques

Chemische Desinfektionsmittel und Antiseptika - Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika

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

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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 14885:2020) 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.

This document will supersede EN 14885:2018.

EN 14885:2018 was revised to update the information on existing standards, to include standards published since 2018 and to give more details how to use the standards for making claims. CEN/TC 216 has prepared a series of standards on chemical disinfectants and antiseptics specifying requirements and test methods. The purpose of this document is to specify the relationship of the various standards to one another and to claims and use recommendations.

To allow for different requirements in different areas of application, separate tests and pass criteria have been or will be prepared for each of the following three areas of application: medical, veterinary, and a group comprising food, industrial, domestic and institutional areas.

This document only refers to test methods which are currently included in the work programme of CEN/TC 216 and which are described in Clause 2. It is likely that additional standards which relate to specific situations will be produced at a later time.

This document was revised to adapt it to the latest state of CEN/TC 216, to correct errors and ambiguities. The following is a list of significant changes since the last edition:

Scope (Clause 1): the different working groups added; safety issues when performing the tests addressed as well as the information that EN 14885 is periodically updated

Normative references (2) updated, the standards revised after the last revision of EN 14885 are signposted.

Terms and definitions (3) *deleted*: “bactericide”, “fungicide” and similar ones; *added:* “active substance”, “contact time”, “limiting test organism”, “test”; *changed*: “antisepsis”, “chemical disinfection”, “virucidal activity”, “microbistatic activity” defined for all other deleted ” -static” definitions, “product”, ”test organism”

Clarification of the text in 4.2.4 as well as in 4.2.5 (former “4.2.5” to “4.2.8”)

New: clarification, that in all standards EN 12353 has to be followed (new 4.2.6)

Special guidance for certain cases of chemo-thermal disinfection (new 4.2.7)

Information about concentrations to be tested (new 4.2.8)

Medical area (4.3), Veterinary area (4.4) and Food, industrial, domestic and institutional areas (4.5) tables and text updated including the clarification for disinfectants used in veterinary care facilities (medical or veterinary)

Clarification of the text in Clauses 5, 6, 7 and 8

The text of Annexes B and C are significantly changed

New Annex D “Differentiation of active and non-active substances in a product”

New Annex E “Choice of meaningful concentrations when testing products according to the standards”

New Annex F “CEN /TC 216 standards in preparation or under revision”

The changes mentioned above have no impact on the use of test results obtained with reference to the former version of EN 14885 if a standard has not been revised in the meantime. Those results are still valid. If there is a new edition in Clause 2 cited (standard revised) refer to the information in Clause 8.

Introduction

This document specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development. This document is not intended to represent disinfection policy guidelines, i.e. guidelines for choosing and assessing the suitability of products for particular situations.

The CEN standards relate to only a limited range of microbial species. These have been chosen as representative species taking into account their relative resistance and their relevance to practical use. The handling properties and the microbiological safety have also been considered in choosing the test organisms.

The test methods in this document are based on the current scientific state of the art. It is recognized that at the present time there is only limited knowledge regarding the relationship between the activity of products as determined by suspension as compared with surface tests, and the relevance of the results of both tests to conditions of use.

Chemical disinfectants and antiseptics should always be used responsibly. This should take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.

1 Scope

This document specifies the European Standards to which products have to conform in order to support the claims for microbicidal activity which are referred to in this document.

This document also specifies terms and definitions which are used in European Standards.

It is applicable to products for which activity is claimed against the following microorganisms: vegetative bacteria (including mycobacteria and *Legionella*), bacterial spores, yeasts, fungal spores and viruses (including bacteriophages).

It is intended to:

a) enable manufacturers of products to select the appropriate standards to be used in order to provide data which support their claims for a specific product;

b) enable users of the product to assess the information provided by the manufacturer in relation to the use for which they intend to use the product;

c) assist regulatory authorities in assessing claims made by the manufacturer or by the person responsible for placing the product on the market.

It is applicable to products to be used in the area of human medicine, the veterinary area and in food, industrial, domestic and institutional areas.

In the area of human medicine (Working Group 1, i.e. WG 1), it is applicable to chemical disinfectants and antiseptics to be used in areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care

— in hospitals, in community medical facilities, dental institutions and medical laboratories for analyses and research,

— in clinics of schools, of kindergartens and of nursing homes,

— and may also occur in the workplace and in the home. It may also include services such as in laundries and kitchens supplying products directly for the patient.

In the veterinary area (WG 2) it is applicable to chemical disinfectants and antiseptics to be used in the areas of breeding, husbandry, veterinary care facilities, production, transport and disposal of animals and veterinary laboratories for analyses and research. It is not applicable to chemical disinfectants used in the food chain following death and entry to the processing industry.

In food, industrial, domestic and institutional areas (WG 3) it is applicable to chemical disinfectants and antiseptics to be used in processing, distribution and retailing of food of animal or vegetable origin. It is also applicable to products for all public areas where disinfection is not medically indicated (homes, catering, schools, nurseries, transports, hotels, offices etc.) and products used in packaging, biotechnology, laboratories (except laboratories for veterinary and medical analyses and research), pharmaceutical, cosmetic etc. industries.

This document is also applicable to active substances and products under development for which no area of application has yet been specified.

This document will be periodically updated to reflect the current published versions of each standard developed in CEN/TC 216. Independent of this update newly published standards should be used, even if they are not yet mentioned in EN 14885.

This document does not refer to methods for testing the toxicological and ecotoxicological properties of products or active substances.

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 1040:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1275:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1276:2019, *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 1499:2013, *Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)*

EN 1500:2013, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)*

EN 1650:2019, *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 1656:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 1657:2016, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - 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 12791:2016+A1:2017, *Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)*

EN 13610:2002, *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)*

EN 13623:2010, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)*

EN 13624:2013, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)*

EN 13697:2015+A1:2019, *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)*

EN 13704:2018, *Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 13727:2012, *+A2:2015,* Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area— Test method and requirements (phase 2, step 1)

EN 14204:2012, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 14347:2005, *Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)*

EN 14348:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)*

EN 14349:2012, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 14476:2013+A2:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)*

EN 14561:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14562:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14563:2008, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)*

EN 14675:2015, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1)*

EN 16437:2014+A1:2019, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16438:2014, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16615:2015, *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2)*

EN 16616:2015, *Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)*

EN 16777:2018, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)*

EN 17111:2018, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 17122:2019, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements - Phase2, step2*

EN 17126:2018, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

NOTE Some recommendations on the use of terminology in the areas of chemical disinfection and antisepsis are given in Annex A.

3.1 Chemical disinfectant or antiseptic procedures and product types

3.1.1
antiseptic
product – excluding antibiotics – that is used to bring about antisepsis

3.1.2
antisepsis
application of an antiseptic on living tissues causing an action on the structure or metabolism of microorganisms to a level judged to be appropriate to prevent and/or limit and/or treat an infection of those tissues

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.10)

3.1.3
chemical disinfectant
product that is capable of chemical disinfection

3.1.4
chemical disinfection
reduction of the number of microorganisms in or on an inanimate or animate matrix, achieved by the irreversible action of a product on their structure or metabolism, to a level judged to be appropriate for a defined purpose

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.10)

Note 2 to entry: Products for antisepsis are excluded

3.1.5
hygienic handrub
treatment of hands by rubbing a product without the addition of water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.6
hygienic handwash
treatment of hands by washing with product and water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.7
instrument disinfection
chemical disinfection of certain instrument surfaces in the medical and veterinary areas by immersion

3.1.8
surface disinfection
chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action

Note 1 to entry: The application includes e.g. wiping, mopping, circulation, flooding, spraying, fogging, etc.

3.1.9
surgical handrub
preoperative treatment of hands by rubbing a product without the addition of water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.10
surgical handwash
preoperative treatment of hands by washing with product and water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.11
textile disinfection
chemical disinfection of textiles through the application of a product by either immersion in a solution or by processing in a washing machine

3.2 Chemical disinfectant or antiseptic action

3.2.1
algaecidal activity
capability of a product to reduce the quantity of algae as test organisms, specified in the corresponding standard(s), under defined conditions

3.2.2
bactericidal activity
capability of a product to reduce the number of viable bacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.3
fungicidal activity
capability of a product to reduce the number of viable yeast cells and mould spores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.4
microbicidal activity
microbiocidal activity
capability of a product to reduce the number of relevant test organisms including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts, specified in the corresponding standard(s)

Note 1 to entry: The above term is a general term, not to be used for claims according to Clause 7 c).

3.2.5
microbistatic activity
microbiostatic activity
capability of a product to inhibit the growth of relevant test organisms, including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts under defined conditions

Note 1 to entry: The above term and related terms like “bacteriostatic”, “fungistatic” are used in CEN / TC 216 standards but cannot be used for claims according to the scope (Clause 1).

3.2.6
mycobactericidal activity
capability of a product to reduce the number of viable mycobacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.7
oocysticidal activity
capability of a product to reduce the number of oocysts of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.8
phagocidal activity
capability of a product to reduce the number of infectious bacteriophage particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.9
sporicidal activity
capability of a product to reduce the number of viable bacterial endospores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.10
tuberculocidal activity
capability of a product to reduce the number of viable cells of relevant Mycobacteria as test organism, specified in the corresponding standard(s), under defined conditions

3.2.11
virucidal activity levels
there are three different levels of virucidal activity: virucidal activity (3.2.11.1), limited spectrum virucidal activity (3.2.11.2) and virucidal activity against enveloped viruses (3.2.11.3)

3.2.11.1
virucidal activity
capability of a product to reduce the number of infectious virus particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

Note 1 to entry: virucidal activity covers enveloped and non-enveloped viruses

3.2.11.2
limited spectrum virucidal activity
capability of a product to reduce the number of infectious virus particles using certain non-enveloped viruses as test organisms, specified in the corresponding standard(s), under defined conditions, thus covering virucidal activity against these test organisms, and additionally defined other non-enveloped virus(es) and all enveloped viruses

3.2.11.3
virucidal activity against enveloped viruses
capability of a product to reduce the number of infectious virus particles using relevant enveloped viruses as test organism, specified in the corresponding standard(s), thus covering activity against all enveloped viruses.

3.2.12
yeasticidal activity
capability of a product to reduce the number of viable yeast cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.3 General terms

3.3.1
active substance
substance or microorganism that has an action on or against harmful organisms

[SOURCE: Biocide Product Regulation (EU) 528/2012, Article 3(1)(c)]

Note 1 to entry: In CEN/TC 216 only chemical substances are used as active substances.

Note 2 to entry: The term "harmful organism" encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts) and viruses (including bacteriophages), algae and oocysts.

Note 3 to entry: In CEN/TC 216 the term “product” encompasses “active substance”.

3.3.2
additional test conditions
test conditions in a standard that are optional and not obligatory, that may be used for further specific product claims and/or applications

Note 1 to entry: Such test conditions can be found in the same or in an additional standard.

3.3.3
contact time
time period during application of the product in a test that elapses between its first contact with the test organisms, and its neutralization

3.3.4
interfering substance
see “soiling”

3.3.5
limiting test organism
test organism that requires the highest concentration to give the specified decimal logarithm (lg) reduction (it is the least susceptible test organism to the product in the chosen experimental conditions)

3.3.6
neutralization
process that suppresses the residual microbicidal activity of a product or active substance within a specific test but does not inactivate or inhibit the test organism using neutralizer and/or dilution (e.g. membrane filtration)

3.3.7
neutralizer
chemical agent or formulation that is used for neutralization

3.3.8
product
formulation used as a chemical disinfectant or antiseptic

Note 1 to entry: A ready-to-use product is a product used undiluted.

Note 2 to entry: The term “product” encompasses “active substance(s)”

3.3.9
product claim
any claim derived from results of one or more test(s) (3.3.11).

3.3.10
soiling
see clean conditions (3.3.10.1) and dirty conditions (3.3.10.2)

Note 1 to entry: The term “soiling” is represented in the standards by the term “interfering substance”

3.3.10.1
clean conditions
conditions representative of surfaces which have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called "low level soiling". The term "low level soiling" has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.10.2
dirty conditions
conditions representative of surfaces which are known to or may contain organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called "high level soiling". The term "high level soiling" has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.11
test
technical operation that consists of the determination of one or more characteristics or performance of a given product or process according to a specified procedure based on the requirements for a specific intended use or application

[SOURCE: EN ISO 16484-2:2004-08 and ISO EN 9000:2015-11, modified]

3.3.12
test organism
strain of a microorganism selected for testing a product within a standardized test

Note 1 to entry: For the purpose of this document, the term microorganism includes vegetative bacteria, bacterial spores, yeasts, mould spores and viruses (including bacteriophages), algae and oocysts.

4 Procedures for claiming activity

4.1 Category of tests

The tests are categorized on a modular basis as follows:

— **Phase 1 tests** are quantitative suspension tests to establish that a product under development has bactericidal, fungicidal, yeasticidal or sporicidal activity without regard to specific areas of application. Phase 1 tests cannot be used for any product claim.

— **Phase 2** comprises two steps:

a) **Phase 2, step 1 tests** are quantitative suspension tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal, virucidal, phagocidal, algaecidal or oocysticidal activity under simulated practical conditions appropriate to its intended use;

b) **Phase 2, step 2 tests** are quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal, virucidal or phagocidal, algaecidal or oocysticidal activity when applied to a surface or skin under simulated practical conditions (e.g. surface, instrument, laundry, handwash and handrub tests);

— **Phase 3 tests** are field tests under practical conditions. Applicable methodologies for this type of test are not yet available, but may be developed in the future. Guidance on the design of phase 3 tests and the use of data from phase 3 tests is provided in Annex C.

NOTE In the following phase 2, step 1 is mostly shortened to “2,1” or “2/1” and phase 2, step 2 to “2,2” or “2/2”.

Phase 2, step 1 tests prove the irreversible inactivation of microorganisms. This test design provides relevant information about the activity of the product against microorganisms in suspension. Desiccated microorganisms may be stressed and may pose different challenges.

Phase 2, step 2 tests provide information about the activity against desiccated microorganisms on inanimate surfaces or on living tissues or against non-desiccated microorganisms on living tissues.

Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time and interfering substances) shall be carried out as specified in the standard.

Phase 2, step 1 and phase 2, step 2 tests are generally needed in combination to support efficacy claims for chemical disinfectants or antiseptics. Only in exceptional cases deviation from this principle is allowed (see relevant applications below and Annex B). Both results shall be taken into account in determination of the label claim.

4.2 General

4.2.1 In order to determine that an active substance has microbicidal properties, it may be tested in accordance with and shall conform to the relevant test conditions and requirements of the European phase 1 standards (EN 1040, EN 1275, EN 14347).

4.2.2 For the medical area see 4.3, for the veterinary area see 4.4, for the food, industrial, domestic and institutional areas see 4.5. The standards specified in 4.3, 4.4 or 4.5 may be used to support product claims of activity/conformity to this European Standard on the basis of criteria specified in those standards (minimum requirements, obligatory and/or specified additional conditions).

4.2.3 When recommendations for use are made based on the standards referenced in EN 14885 these shall be supported by test results relevant for this recommendation, e.g. a result for 30 min contact time does not allow a claim for 10 min (but a result for 10 min allows a claim for 30 min if the same product concentration is recommended for use). It is not possible to extend or shorten the time for use beyond the limits (i.e. the minimum and maximum *additional* contact times in the medical, veterinary, food, industrial, domestic and institutional areas) specified in standards referred to in EN 14885 to claim conformity to the standard (see also 4.2.5.3).

4.2.4 The product marketed shall be equivalent to the one tested. Equivalent means that it contains the same active substances in the same quantity. If non-active substances have been changed in the formulation it has to be demonstrated by theoretical evaluation and/or appropriate experimentation that this change has no impact on the product’s activity. The method(s) to establish that the changes have no impact on the product's activity shall be chosen taking into account the efficacy test(s) performed to support the claim of the original product and the nature of the change and its potential influence on the product's characteristics including the claim.

4.2.5 Where there is no appropriate standard for an application within a specific area, a standard from another area may be recommended for use. If later on an appropriate standard is published, this new standard shall be used. Special cases:

4.2.5.1 Where in EN 14885 no standard exists for a specific activity in an area (e.g. medical), a standard from another area (e.g. veterinary) may be used and test conditions modified for relevance to the area of application to match the specific application. In certain cases it may be necessary or recommendable to modify even the test organism(s) to match the requirements of the area. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.5.2 Where in EN 14885 there is no intention to develop a test for specific product activity, the methodology in a standard specified in EN 14885 may be used and test conditions modified to match the required activity. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.5.3 Where in EN 14885 no standard exists that specifies the use conditions for a specific product activity in an area (e.g. activity at a temperature or contact time not specified in the minimum requirements/obligatory or additional test conditions), a standard may be used with the relevant test condition modified for relevance to the area of application. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.6 All test organisms shall be preserved and kept according to EN 12353 taking into account the specific instructions in the standard used. If additional test organisms are used the principles laid down in EN 12353 and in the standard used shall be followed as far as it is feasible and sensible. Deviations from these principles shall be scientifically justified.

4.2.7 Chemo-thermal disinfection processes are relevant in several application areas. Elevated temperatures may for example help to reduce the amount of chemicals necessary to achieve the desired goal. While for the bactericidal and virucidal efficacy spectrum relevant specific thermo-resistant test organisms have been defined for test temperatures > 40 °C and some application areas, this has not yet been achieved for other efficacy spectra and application areas. It may, however, be desirable to provide data on e.g. yeasticidal, fungicidal and/or mycobactericidal effect of chemo-thermal disinfection. Due to the limited temperature resistance of these test organisms this may lead to invalid controls of experimental conditions (control A/water control in some tests). Such tests may deliver appropriate e.g. yeasticidal, fungicidal and/or mycobactericidal results under chemo-thermal conditions. In such cases control A and/or water control shall be run in parallel at application temperature and at 20 °C. If control A and/or water control at 20 °C demonstrates the validity of the test and the efficacy at elevated temperatures is shown, the product can be considered active.

By implementing the additional control A (and water control, if applicable) at 20 °C the standard used shall be regarded validated for any temperature below the temperatures that are known to bring about mere thermal disinfection for the chosen contact time.

The same approach can also be chosen, if bactericidal and virucidal tests are conducted at temperatures > 60°C. In these instances, control A (and water control, if applicable) shall be performed at 60°C for the relevant thermo-resistant test organisms (instead of 20°C) in addition to the application temperature.

4.2.8 All phase 2, step 1 and most of phase 2, step 2 CEN/TC216 standards require that a product shall be tested at a minimum of three different concentrations to include at least one concentration in the active range and one concentration in the non-active range. For environmental, occupational health and economic reasons, products at their use concentration should not contain more active substances than necessary (see Annex E for guidance to test meaningful concentrations).

4.2.9 All CEN/TC 216 tests have to be conducted in accordance with all applicable European, national and local safety guidelines.

4.3 Chemical disinfectants and antiseptics for use in the medical area

4.3.1 General

In order to make a claim that a product has disinfectant properties, suitable for use in the medical area, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 1 as specified for the particular type of product and its spectrum of activity (e.g. bactericidal, fungicidal etc.). Table 1 includes the information on standards in preparation or planned (see also Annex F).

Table 1 — Medical area – Standard test methods for substantiating product claims

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection			Instrument Disinfection	Textile Disinfection	Aqueous systems
					mechanical action		Air-borne			
					without	with				
Bactericidal	2,1	EN 13727 (handrub products under clean, handwash products under dirty conditions)			EN 13727		***	EN 13727	**	***
	2,2	EN 1500	EN 1499	EN 12791	*	EN 16615	*	EN 14561	EN 16616	***
Yeasticidal	2,1	EN 13624 (handrub products under clean, handwash products under dirty conditions)			EN 13624		***	EN 13624	*	***
	2,2	***			*	EN 16615	*	EN 14562	EN 16616	***
Fungicidal	2,1	***			EN 13624		***	EN 13624	*	***
	2,2	***			*	**	*	EN 14562	EN 16616	***
Tuberculocidal	2,1	EN 14348	EN 14348	***	EN 14348		***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**	**	*	EN 14563	EN 16616	***

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection			Instrument Disinfection	Textile Disinfection	Aqueous systems
					mechanical action		Air-borne			
					without	with				
Mycobactericidal	2,1	EN 14348	EN 14348	***	EN 14348		***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**	**	*	EN 14563	EN 16616	***
Virucidal against enveloped viruses	2,1	EN 14476	EN 14476	***	EN 14476		***	**	**	***
	2,2	**	**	***	EN 16777	**	***	EN 17111	**	***
Limited spectrum virucidal	2,1	EN 14476	EN 14476	***	EN 14476		***	***	**	***
	2,2	*	**	***	EN 16777	**	***	***	**	***
Virucidal	2,1	EN 14476	EN 14476	***	EN 14476		***	EN 14476	EN 14476 (dirty cond.)	***
	2,2	*	***	***	EN 16777	**	*	EN 17111	**	***
Sporicidal against *C. diff.*	2,1	***			EN 17126		***	EN 17126	EN 17126	***
	2,2	***			**	**	***	**	***	***
Sporicidal	2,1	***			EN 17126		***	EN 17126	EN 17126	***
	2,2	***			**	**	*	**	***	***
Legionella	2,1	***			***		***	***	***	EN 13623
	2,2	***			***		***	***	***	***

* Work item approved (see Annex F).

** No work item yet approved but relevant standards may become available in the future

*** No intention to develop a test.

As stated under 4.1, phase 2, step 1 and phase 2, step 2 tests shall be passed for any claim if standards are available. All products in the medical area shall pass the standards for bactericidal and yeasticidal activity as a minimum requirement except those products exclusively claiming activity against *Legionella* or fungicidal or sporicidal activity. A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in 4.3.2 and in Tables 2, 3, 4 and 5. It is also stated, if for a certain field of application more than one standard shall be passed (see also Annex B).

4.3.2 Fields of application / Standards necessary to be passed for basic and additional label claims

4.3.2.1 General

In 4.3.2.2 to 4.3.2.9 the obligatory and additional standards for a defined claim are described. The Tables 2, 3, 4, 5 and 6 (4.3.3) give an overview of the standards relevant for the medical area and their

main features, such as test organisms, temperature, soiling, contact time and reduction. The term "soiling" means always the soiling used within the medical area (e.g. 5.2.2.8 in EN 13727) even if a standard from another area (e.g. food) is used according to 4.2.5.1. In Table 5 specific aspects how to use EN 14348 for the different fields of application are laid down.

Veterinary care facilities and laboratories are covered by the standards for the medical area in case of: hygienic handrub and handwash, surgical handrub and handwash.

4.3.2.2 Hygienic handrub

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1500 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1)

NOTE Activity on mould spores is not regarded relevant for hygienic handrub products.

4.3.2.3 Hygienic handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1499 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1)

NOTE Activity on mould spores is not regarded relevant for hygienic handwash products.

4.3.2.4 Surgical handrub and handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 12791 (2/2)
Yeasticidal activity	EN 13624 (2/1)

NOTE Activity on mould spores, mycobacteria and viruses, is not regarded relevant for surgical handrub and surgical handwash according to the state of the art.

4.3.2.5 Instrument disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 14561 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 14562 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 14562 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1), EN 14563 (2/2)
Virucidal activity against enveloped viruses / Virucidal activity	EN 14476 (2/1)[a], EN 17111 (2/2)
Sporicidal activity against *C. diff.*/ Sporicidal activity	EN 17126 (2/1)

4.3.2.6 Surface disinfection without mechanical action

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1)
Yeasticidal activity	EN 13624 (2/1)
Bactericidal / Yeasticidal	EN 13697 (2/2) [a]
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 13697 (2/2) [a]
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1), EN 16777 (2/2)
Sporicidal activity against *C. diff.*/ Sporicidal activity	EN 17126 (2/1)

[a] Apply this standard for the medical area with following altered conditions (according to the manufacturer's requirements):

- temperature between 4 °C to 30 °C,

- soiling: clean conditions or dirty condition for the medical area,

- contact time: 5 min or shorter for surfaces that are likely to come into contact with patients or staff close to the patient and “multitouch” surfaces, for other surfaces not longer than 60 min.

The lg reduction to be achieved shall be ≥ 5,0 for bactericidal activity and ≥ 4,0 for yeasticidal and fungicidal activity. The initial inoculum may be increased by max. 1,0 lg to achieve the required lg-reduction.

4.3.2.7 Surface disinfection with mechanical action

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 16615 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 16615 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1)
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity /Virucidal activity	EN 14476 (2/1)
Sporicidal activity against *C. diff.*/ Sporicidal activity	EN 17126 (2/1)

4.3.2.8 Textile disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1, dirty conditions), EN 16616 (2/2)
Yeasticidal activity	EN 13624 (2/1, dirty conditions), EN 16616 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1, dirty conditions), EN 16616 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1, dirty conditions), EN 16616 (2/2)
Virucidal activity	EN 14476 (2/1, dirty conditions)
Sporicidal activity against *C. diff.*/ Sporicidal activity	EN 17126 (2/1)

4.3.2.9 Water treatment for control of *Legionella*

See EN 13623 in Table 2 below.

4.3.3 Overview of the standards relevant for the medical area and their main features

Table 2 — Medical area – Test conditions and requirements of standard test methods for bactericidal activity of products

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 1499 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538 (=NCIMB 10083)	tested on the skin	between 30 s and 1 min	none	product > reference soap with 1 min wash (p = 0,01)
EN 1500 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538	tested on the skin	between 30 s and 1 min	none	product not < Propan-2-ol 60 % vol with 2 × 3 ml/30 s each (p = 0,025)
EN 12791 2,2	Minimum test conditions				
	normal skin flora	tested on the skin	between 1 min and 5 min	none	<u>Immediate effect:</u> product not < Propan-1-ol 60 % vol with n × 3 ml/3 min (p = 0,025)
					<u>3-h-effect:</u> product not < Propan-1-ol 60 % vol (p = 0,025)
	Additional test conditions				
	none	none	none	none	<u>Sustained effect</u>: product > Propan-1-ol 60 % vol with n × 3 ml/3 min after 3 h (p = 0,01)

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 13727 2,1	Hygienic handwash and handrub minimum test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	20	between 30 s and 1 min	Clean conditions (handrub): bovine albumin: 0,3 g/l Dirty conditions (handwash): bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 5,0 for handrub products ≥ 3,0 for handwash products
	Surgical handwash and handrub minimum test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	20	between 1 min and 5 min	Clean conditions (handrub): bovine albumin: 0,3 g/l Dirty conditions (handwash): bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Instrument disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 When temperature is 40 °C or higher: only *Enterococcus faecium* ATCC 6057	between 20 and 70	no longer than 60 min	Clean conditions bovine albumin: 0,3 g/l and/or Dirty conditions bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Surface disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	between 4 and 30	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions bovine albumin: 0,3 g/l and/or Dirty conditions bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Additional conditions (all uses)				
	any relevant test organism	none	none	any relevant interfering substance	none

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 13623 2,1	Obligatory test conditions				
	Legionella pneumophila subsp. *pneumophila* ATCC 33152	30 cooling water	15 h slow acting products 1 h fast acting products	for testing, 0,05 % yeast extract solution buffered ferrous hard water for treatment of cooling water	≥ 4,0
		20 water for general purposes		for testing, 0,05 % yeast extract solution hard water for general purposes	
	The following additional test conditions are permitted:				
	any *Legionella* strain, e.g. *Legionella pneumophila* serogroup 1 Benidorm (NCTC 12006, ATCC 43108)	no additional temperatures are considered relevant to this test	2 h, 6 h, 40 h, 48 h	no additional interfering substances are considered relevant for this test	
EN 14561 2,2	Obligatory test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	20	60 min	<u>Clean conditions:</u> bovine albumin 0,3 g/l and/or <u>Dirty conditions:</u> bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 5,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 16615 2,2	Obligatory test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	between 4 and 30	as recommended by the manufacturer, but no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces) minimum contact time: 1 min	<u>Clean conditions:</u> bovine albumin 0,3 g/l and/or <u>Dirty conditions:</u> bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 5,0 (field 1) and an average of ≤ 50 cfu/25 cm² (on fields 2 to 4)
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	none
EN 16616 2,2	Obligatory test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 *Escheria coli* (K12) ATCC 10538 *Enterococcus faecium* ATCC 6057 (>60 °C)	as recommended by the manufacturer	as recommended by the manufacturer	- 12,5 ml sheep blood/kg textile -	≥ 7,0
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	none

Table 3 — Medical area – Test conditions and requirements of standard test methods for fungicidal and yeasticidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 13624 2,1	Hygienic handwash and handrub				
	yeasticidal activity: only *Candida albicans* ATCC 10231	20	between 30 s and 1 min	Clean conditions (handrub): bovine albumin: 0,3 g/l Dirty conditions (handwash): bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 4,0 for handrub products ≥ 2,0 for handwash products
	Surgical handwash and handrub				
	yeasticidal activity: only *Candida albicans* ATCC 10231	20	between 1 min and 5 min	Clean conditions (handrub): bovine albumin: 0,3 g/l Dirty conditions (handwash): bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 4,0
	Instrument disinfection				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis* ATCC 16404	between 20 and 70	no longer than 60 min	Clean conditions bovine albumin: 0,3 g/l and/or Dirty conditions bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 4,0

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
	Surface disinfection				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis* ATCC 16404	between 4 and 30	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions bovine albumin: 0,3 g/l and/or Dirty conditions bovine albumin: 3,0 g/l plus sheep erythrocytes: 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	none	none	any relevant interfering substance	none
EN 14562 2,2	Obligatory test conditions				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus niger*[a] ATCC 16404	20	60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C steps	5 min, 15 min, 30 min		
EN 16615 2,2	Obligatory test conditions				
	yeasticidal activity: *Candida albicans* ATCC 10231	4 to 30	as recommended by the manufacturer, but no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces) minimum contact time: 1 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0 (field 1) and an average of ≤ 50 cfu/25 cm^2 (on fields 2 to 4)

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	none
EN 16616 2,2	Obligatory test conditions				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis* ATCC 16404	as recommended by the manufacturer	as recommended by the manufacturer	12,5 ml sheep blood/kg textile	≥ 6,0
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	none
a The name of "*Aspergillus niger* ATCC 16404" has been changed to "*Aspergillus brasiliensis* ATCC 16404".					

Table 4 — Medical area – Test conditions and requirements of standard test methods for virucidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 14476 2,1	Hygienic handrub and handwash[d]				
	virucidal activity against enveloped viruses: Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 or strain Elstree, ATCC VR-1549 **limited spectrum virucidal activity[a]:** Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin **virucidal activity:** Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin	20	between 30 s and 2 min	Clean conditions (handrub): bovine albumin 0,3 g/l Dirty conditions (handwash): bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0 for handrub products ≥ 2,0 for handwash products
	Instrument disinfection				
	Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin **when Temperature is 40°C or higher, only** Murine parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346	between 20 and 70	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	Surface disinfection				
	virucidal activity against enveloped viruses: Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 or strain Elstree, ATCC VR-1549 **limited spectrum virucidal activity[a]:** Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin **virucidal activity:** Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin	between 4 and 30	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
	Textile disinfection				
	Murine parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346	between 30 and 70	no longer than 20 min	Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	n.a.
EN 16777 2,2	Minimum test conditions				
	virucidal activity against enveloped viruses: Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 or strain Elstree, ATCC VR-1549 **limited spectrum virucidal activity[a]:** Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin **virucidal activity[b]:** Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin	between 18 and 25	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	4 30	any relevant contact time	any relevant interfering substance	≥ 4, 0
EN 17111 2,2	Obligatory test conditions				
	virucidal activity against enveloped viruses[c]: Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 or strain Elstree, ATCC VR-1549 **virucidal activity[b]:** Adenovirus, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin **when Temperature is 40°C or higher, only** Murine parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346	between 20 and 70	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	≥ 4,0

a The test for "limited spectrum virucidal activity" will cover all enveloped viruses (Annex A) and norovirus, rotavirus and adenovirus.

b The test for "virucidal activity poliovirus (as used in the corresponding suspension test) cannot be used for surfaces, because of drying problems.

c **Pre-cleaning products** with a combined cleaner/ chemical disinfectant

d Due to the mode of administration hygienic handwash products can only be tested at a maximum concentration of 50 % (i.e. 62.5 % in EN 14476). Thus virucidal activity against enveloped viruses can be claimed for these products only. For this claim, i.e. virucidal activity against enveloped virusesa logarithmic reduction factor ≥ 2 lg RF is requested, which is relevant for hygienic handwash products only.

Table 5 — Medical area – Test conditions and requirements of standard test methods for mycobactericidal and tuberculocidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 14348 2,1	Obligatory test conditions				
	tuberculocidal activity: only *Mycobacterium terrae* ATCC 15755 or **mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		≥ 4,0

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time**	**Interfering substances**	**Logarithmic reduction** expressed in lg
Remark EN 14348 can be used to demonstrate mycobactericidal and/or tuberculocidal activity for hygienic handrub (4.3.2.2) and – wash (4.3.2.3) products, surface disinfectants (4.3.2.6 and 4.3.2.7) and chemical disinfectants for textile (4.3.2.8). In these cases the contact times shall be adapted according to the principles described in EN 13727 and EN 13624.					
EN 14563 2,2	**tuberculocidal activity**: *Mycobacterium terrae* ATCC 15755 or **mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		
EN 16616 2,2	Obligatory test conditions				
	tuberculocidal activity: *Mycobacterium terrae* ATCC 15755 or **mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755	as recommended by the manufacturer	as recommended by the manufacturer	12,5 ml sheep blood/kg textile	≥ 7,0
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	≥ 4,0

Table 6 — Medical area – Test conditions and requirements of standard test methods for sporicidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 17126 2,1	Surface disinfection				
	sporicidal activity: Spores of *Bacillus subtilis* ATCC 6633 Spores of *Bacillus cereus* CIP 105151 **sporicidal activity against *Clostridium difficile*:** Spores of *Clostridium difficile* NCTC 13366	between 4 and 30	no longer than 15 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	Instrument disinfection				
	sporicidal activity: Spores of *Bacillus subtilis* ATCC 6633 Spores of *Bacillus cereus* CIP 105151 **sporicidal activity against *Clostridium difficile*:** Spores of *Clostridium difficile* NCTC 13366	between 20 and 70	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	Textile disinfection				
	sporicidal activity: Spores of *Bacillus subtilis* ATCC 6633 Spores of *Bacillus cereus* CIP 105151 **sporicidal activity against *Clostridium difficile*:** Spores of *Clostridium difficile* NCTC 13366	between 20 and 80	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/l and/or Dirty conditions: bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant test organism	none	none	any relevant interfering substance	≥ 4,0

4.3.4 Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time, diluents and interfering substances) shall be carried out as specified in the standard. Additional claims which can be made are given in 4.3.2 and the Tables 2, 3, 4, 5 and 6. Products that are tested under clean conditions are generally meant to be used on visibly clean surfaces, incl. living tissues like hands.

If for a defined claim it is necessary to pass more than one standard, the test conditions shall be the same in all the standards (e.g. instrument disinfection bactericidal and fungicidal activity: 4 min contact time, clean conditions, 30 °C; these test conditions are tested in EN 13727 and EN 13624 as well as in EN 14561 and EN 14562), the contact time may be shorter than the one claimed in accordance with 4.2.3.

4.4 Chemical disinfectants and antiseptics for use in the veterinary area

4.4.1 General

In order to claim that a product has disinfectant properties, suitable for use in the veterinary area, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 7 as specified for the particular type of product and its spectrum of activity (e.g. bactericidal, fungicidal etc.).

Tests shall be carried out under the obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, interfering substances, contact time) shall be carried out as specified in the standard. Additional conditions which can be used are given in Tables 8 to 11.

If for a defined claim it is necessary to pass more than one standard, the test conditions shall be the same in all standards e.g. for a claim of additional bactericidal activity at 4 °C, 30 min contact time under high soiling conditions, test conditions in EN 1656 and EN 14349 shall be 30 min contact time, high soiling level and 4 °C.

Laboratories for veterinary analyses and examination and operating areas, including instruments used for veterinary applications, are covered by the medical standards but with test organisms for the veterinary area; all other areas such as waiting rooms, if soiled, and recovery housing fall under the veterinary standards.

Table 7 — Veterinary area – Standard test methods to be used to substantiate claims for products

Type of activity	Phase Step	Product Claim / Field of application			
		General Surface Disinfection without mechanical action [a]	Teat Disinfection	Disinfection of equipment by Immersion	Hygienic hand wash [b]
Bactericidal	2.1	EN 1656	EN 1656	EN 1656	EN 13727
	2.2 non-porous	EN 14349	***	EN 14349	***
	2.2 porous	EN 16437 + A1	*	***	EN 1499
Fungicidal	2.1	EN 1657	***	EN 1657	***
	2.2 non-porous	EN 16438	***	EN 16438	***

Type of activity	Phase Step	Product Claim / Field of application			
		General Surface Disinfection without mechanical action [a]	Teat Disinfection	Disinfection of equipment by Immersion	Hygienic hand wash [b]
	2.2 porous	**	***	***	***
Yeasticidal	2.1	EN 1657	EN 1657	EN 1657	EN 13624
	2.2 non-porous	EN 16438	***	EN 16438	***
	2.2 porous	**	***	**	***
Mycobactericidal	2.1	EN 14204	***	EN 14204	***
	2.2 non-porous	**	***	**	***
	2.2 porous	**	***	***	***
Virucidal	2.1	EN 14675	***	EN 14675	EN 14476
	2.2 non-porous	EN 17122	***	**	***
	2.2 porous	**	***	**	***
Sporicidal	2.1	**	***	**	***
	2.2 non-porous	***	***	***	***
	2.2 porous	***	***	***	***
Oocysticidal	2.1	***	***	***	***
	2.2 non-porous	**	***	**	***
	2.2 porous	***	***	***	***

a There are no work items approved in the veterinary area for general surface disinfection with mechanical action but relevant standards may become available in the future

b See 4.3.2.3 for details.

* Work item approved (see Annex F).

** No work item yet approved but relevant standards may become available in the future.

*** No intention to develop a test.

In any case the product shall pass the standards for bactericidal and yeasticidal activities as a minimum requirement except those products exclusively claiming fungicidal, sporicidal or virucidal activity. A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in Table 8 to 11. If for a certain field of application more than one standard has to be passed it is indicated in notes to the tables (see also Annex B).

4.4.2 Overview of the standards relevant for the veterinary area and their main features

Table 8 — Veterinary area – Test conditions and requirements of standard test methods for bactericidal[a] activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time Min	Interfering substances	Logarithmic reduction expressed in lg
EN 1656 2,1	Surface disinfection				
	Pseudomonas aeruginosa ATCC 15442 *Proteus hauseri* ATCC 13315[b] *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	5 to 40 (at intervals of 5 °C)	Any between 1 and 120 at intervals of 30 s from 30 s to 5 min and at intervals of 5 min from 5 min to 120 min	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 5,0
	The following additional test conditions are permitted				
	any relevant bacteria	none	none	any relevant substance	≥ 5,0
EN 1656 2,1	Post-milking teat disinfection[c]				
	Escherichia coli ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436	20 to 30 (at intervals of 5 °C)	Any between 1 and 30 at intervals of 30 s from 30 s to 5 min and at intervals of 5 min from 5 min to 30 min	10 g/l milk powder	≥ 5,0
	The following additional test conditions are permitted:				
	any relevant bacteria	none	none	any relevant substance	≥ 5,0
EN 1656 2,1	Pre-milking teat disinfection[c]				
	Escherichia coli ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436	(20 to 30) (at intervals of 5 °C)	Any between 0,5 and 3 at intervals of 30 s	3 g/l bovine albumin	≥ 5,0
	The following additional test conditions are permitted:				
	any relevant bacteria	none	none	any relevant substance	≥ 5,0

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** Min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 14349 2,2 Non-porous surface	Obligatory test conditions				
	Pseudomonas aeruginosa ATCC 15442 *Proteus vulgaris*[d] ATCC 13315 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	10	30	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant bacteria	4, 20, 40	1, 5, 60	any relevant substance	≥ 4,0
EN 16437+A1 2,2 Porous surface	Obligatory test conditions				
	Enterococcus hirae ATCC 10541 *Proteus vulgaris*[d] ATCC 13315 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538	10	any of 1, 5,15. 30 and then at 30 min intervals up to 360	low-level soiling: 3 g/l bovine albumin	≥ 4,0
	The following additional test conditions are permitted				
	any relevant bacteria	4, 20, 40	none	any relevant substance	≥ 4,0

[a] In order to claim bactericidal activity for general surface disinfection or disinfection by immersion it is necessary to provide data from both phase 2, step 1 EN 1656 and phase 2 step 2

EN 14349 or EN 16437 tests.

[b] The strain was formerly named: *P. vulgaris* (

[c] In order to claim bactericidal activity for teat disinfection it is necessary to provide data from both phase 2, step 1 EN 1656 and phase 2, step 2 standard when available using obligatory conditions for teat disinfection.

d The strain has been renamed *P. hauseri* and this will be taken into account during the next revisions of EN 16437 and EN 14349

Table 9 — Veterinary area – Test conditions and requirements of standard test methods for yeasticidal[a] and fungicidal[a] activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time min	Interfering substances	Logarithmic reduction expressed in lg
EN 1657 2,1	Surface disinfection				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis* ATCC 16404	10	30	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant fungi or yeasts	4, 20, 40	5, 60, 120	any relevant substance	≥ 4,0
	Post-milking teat disinfection				
	Candida albicans ATCC 10231 (yeasticidal)	30	5	10 g/l reconstituted skimmed milk	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant fungi or yeasts	20	1	any relevant substance	≥ 4,0
	Pre-milking teat disinfection				
	Candida albicans ATCC 10231 (yeasticidal)	30	0,5 (30 s)	10 g/l reconstituted skimmed milk 10 g/l	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant fungi or yeasts	20	1	any relevant substance	≥ 4,0

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 16438 2,2	Obligatory test conditions				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis* ATCC 16404	10	60	low-level soiling: 3 g/l bovine albumin high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 3,0
	The following additional test conditions are permitted				
	any relevant fungi or yeasts	4, 20, 40	5, 30, 120	any relevant substance	≥ 3,0
[a] In order to claim fungicidal or yeasticidal activity for general surface disinfection or disinfection by immersion it is necessary to provide data from both phase 2 step 1 EN 1657 and phase 2 step 2 EN 16438 tests.					

Table 10 — Veterinary area – Test conditions and requirements of standard test methods for virucidal activity of products[b]

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 14675 2,1	Obligatory test conditions				
	Bovine enterovirus Type 1 (ECBO) ATCC VR-248[a]	10	30	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	none	4, 20, 40	1, 5, 60	any relevant substance	
EN 17122 2,2	Obligatory test conditions				
	Virucidal activity Porcine Parvovirus, Strain NADL2 **Virucidal activity against enveloped viruses only** Feline Coronavirus, Strain Munich	10	any of 1, 5, 15, 30, 60 and 120	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 3,0
	The following additional test conditions are permitted:				
	any relevant viruses	4, 20, 40	any relevant time	any relevant substance	≥ 3,0

a The ATCC No has been renamed: enterovirus E (EV-E1) (shall be taken into account during the next revision of EN 14675)

b To claim virucidal activity the product shall pass both EN 14675 with the bovine enterovirus test strain and EN 17122 with the porcine parvovirus test strain.

Table 11 — Veterinary area – Test conditions and requirements of standard test methods for mycobactericidal activity of products

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 14204 2,1	Obligatory test conditions				
	Mycobacterium avium ATCC 15769	10	60	low-level soiling: 3 g/l bovine albumin and/or high-level soiling: 10 g/l bovine albumin plus 10 g/l yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	any relevant mycobacteria	4, 20, 40	1, 5, 10, 15, 30, 120	any relevant substance	≥ 4,0

4.4.2 Tests shall be carried out under the obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, interfering substances, contact time) shall be carried out as specified in the standard. Additional conditions which can be used are given in Tables 8 to 11.

If for a defined claim it is necessary to pass more than one standard, the test conditions shall be the same in all standards e.g. for a claim of additional bactericidal activity at 4 °C, 30 min contact time under high soiling conditions, test conditions in EN 1656 and EN 14349 shall be 30 min contact time, high soiling level and 4 °C.

4.5 Chemical disinfectants and antiseptics for use in food, industrial, domestic and institutional areas

4.5.1 General

In order to make a claim that a product has disinfectant properties, suitable for use in food, industrial, domestic and institutional areas, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 12 as specified for the particular type of product and its claimed spectrum of activity (e.g. bactericidal, fungicidal etc.). Table 12 includes the information on standards in preparation or planned (see also Annex F). A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in Tables 13 to 23.

Table 12 — Food, industrial, domestic and institutional area – Standard test methods substantiating product claims

Type and/or purpose of product	Phase, step	Activity claims				
		Bactericidal	Fungicidal	Yeasticidal	Virucidal	Sporicidal
Surface disinfectant without mechanical action Clean conditions	2,1	EN 1276 (clean conditions)	EN 1650 (clean conditions)	EN 1650 (clean conditions)	***	EN 13704
	2,2	EN 13697 (clean conditions) [b]	EN 13697 (clean conditions) [b]	EN 13697 (clean conditions) [b]	**	***
Surface disinfectant without mechanical action Dirty conditions	2,1	EN 1276 (dirty conditions)	EN 1650 (dirty conditions)	EN 1650 (dirty conditions)	***	EN 13704
	2,2	EN 13697 (dirty conditions) [b]	EN 13697 (dirty conditions) [b]	EN 13697 (dirty conditions) [b]	**	***
Surface disinfectant with mechanical action	2,1	EN 1276	EN 1650	EN 1650	***	***
	2,2	**	***	**	***	***
Products used for “cleaning in place”	2,1	EN 1276	EN 1650	EN 1650	EN 13610 (bacterio-phages)	EN 13704
Hygienic handwash	2,1	EN 1276	***	EN 1650**	***	***
	2,2	EN 1499	***	***	***	***
Hygienic handrub	2,1	EN 1276	***	EN 1650**	***	***
	2,2	EN 1500	***	***	***	***
Products for use in breweries [a]	2,1	EN 1276 (breweries)	EN 1650 (breweries)	EN 1650 (breweries)	***	EN 13704
	2,2	EN 13697 (breweries)	EN 13697 (breweries)	EN 13697 (breweries)	**	**
Products used in the beverage and soft drinks industry [a]	2,1	EN 1276 (beverage)	EN 1650 (beverage)	EN 1650 (beverage)	***	EN 13704
	2,2	EN 13697 (beverage)	EN 13697 (beverage)	EN 13697 (beverage)	**	**

Type and/or purpose of product	Phase, step	Activity claims				
		Bactericidal	Fungicidal	Yeasticidal	Virucidal	Sporicidal
Products used in dairies [a]	2,1	EN 1276 (dairies)	EN 1650 (dairies)	EN 1650 (dairies)	EN 13610 (bacterio-phages)	EN 13704
	2,2	EN 13697 (dairies)	EN 13697 (dairies)	EN 13697 (dairies)	***	**
Products used in the cosmetic industry [a]	2,1	EN 1276 (cosmetics)	EN 1650 (cosmetics)	EN 1650 (cosmetics)	***	EN 13704
	2,2	EN 13697 (cosmetics)	EN 13697 (cosmetics)	EN 13697 (cosmetics)	***	***
Products used in the pharmaceutical industry	2,1	EN 1276 (pharmaceutical)	EN 1650 (pharmaceutical)	EN 1650 (pharmaceutical)	***	EN 13704
	2,2	EN 13697 (pharmaceutical)	EN 13697 (pharmaceutical)	EN 13697 (pharmaceutical)	***	***

a The obligatory conditions have to be carried out before additional conditions for a specific use.

b Where applicable.

* Work item approved (see Annex F).

** No work items are yet approved but relevant standards may become available in the future.

*** No intention to develop a test.

4.5.2 Fields of application / Standards necessary to be passed for basic and additional label claims

Tests shall be carried out under the obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, contact time, temperatures, diluents and interfering substances) shall be carried out as specified in the standard. Additional claims which can be made are given in Tables 13 to 23.

Table 13 — Application of standards: dairies

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
CIP (*combined* cleaning and disinfection); e.g. tanks, pipes, filling machines	dirty surfaces, temperature > 40°C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal phagocidal sporicidal	EN 1276 EN 1650 EN 13610 EN 13704	soiling: 10,0 g/l reconstituted skimmed milk (dirty conditions) 40 °C 15 min and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
CIP (clean surface); e.g. tanks, pipes, filling machines	clean surfaces, room temperature or higher 5 min to 30 min	bactericidal fungicidal and/or yeasticidal phagocidal sporicidal	EN 1276 EN 1650 EN 13610 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 10,0 g/l reconstituted skimmed milk (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (clean surface) (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 10,0 g/l reconstituted skimmed milk (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (clean surface) (e.g. wiping)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 10,0 g/l reconstituted skimmed milk (dirty conditions) 20 °C 30 min and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking disinfection without mechanical action (clean surface) (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min

Table 14 — Application of standards: food processing (e.g. meat, fish, prepared food)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20° or ≥ 40 °C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 20 °C and/or 40 °C 15 min and/or 30 min, and/or 60 min
CIP (clean surface); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min to 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping)	dirty surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection with mechanical action (e.g. wiping)	clean surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min and/or 30 min and/or 60 min
crate washers (crates, boxes, buckets, containers etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 10 °C and/or 20 °C 30 min, and/or 60 min

Table 15 — Application of standards: alcoholic beverages (e.g. beer, wine)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. pipes, tanks, filler	dirty surfaces, 4 °C to 20 °C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l yeast extract (dirty conditions) 4 °C and/or 20 °C 15 min and/or 30 min, and/or 60 min
disinfection (CIP) (clean surface); e.g. pipes, tanks, filler	clean surfaces, 4 °C to 20 °C 5 min to 30 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 0,3 g/l bovine albumin solution (clean conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l yeast extract (dirty conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l yeast extract (dirty conditions) 4 °C and/or 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 4 °C and/or 20 °C 30 min and/or 60 min

Table 16 — Application of standards: non-alcoholic beverages (e.g. mineral water, soft drinks)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. pipes, tanks, filler, mixer	dirty surfaces, temperature ≥ 40 °C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l saccharose (dirty conditions) 40 °C 15 min and/or 30 min, and/or 60 min
disinfection (CIP) (clean surface); e.g. pipes, tanks, filler, mixer	clean surfaces, room temperature or higher 5 min to 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l saccharose (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 [a] and EN 13697	soiling: 3,0 g/l bovine albumin solution or 10,0 g/l saccharose (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min

Table 17 — Application of standards: food professional handling (e.g. professional kitchen)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined surface cleaning and disinfection by spraying and/or foaming (e.g. general equipment)	dirty surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. general equipment)	clean surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping of working surfaces)	dirty surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 [a]	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (e.g. wiping of working surfaces)	clean surfaces room temperature and low temperature (10 °C) 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
dish washing machines (dishes, cutlery, cookware, boxes, buckets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumine solution (dirty conditions) 20 °C 30 min and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min

Table 18 — Application of standards: pharmaceutical industry

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20 °C or ≥ 40 °C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 20 °C and/or 40 °C 15 min and/or 30 min, and/or 60 min
CIP (clean surface); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min to 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming[b] (e.g. general equipment)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection by spraying and/or foaming[b] (e.g. general equipment)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action[b] (e.g. wiping of working surfaces)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704[a] EN 14476	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action[a] (e.g. wiping of working surfaces)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
crate washers (crates, boxes, buckets, tablets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 3,0 g/l bovine albumine solution (dirty conditions) 20 °C 30 min and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
[a] In clean rooms sterile and sterile packed chemical disinfectants / detergent chemical disinfectants have to be used.				

Table 19 — Application of standards: cosmetic industry

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20 °C or ≥ 40 °C 15 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution or 5,0 g/l Sodium dodecyl sulphate (dirty conditions) 20 °C and/or 40 ° C 15 min and/or 30 min, and/or 60 min
CIP (clean surface); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min to 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. general equipment)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumin solution or 5,0 g/l Sodium dodecyl sulphate (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. general equipment)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping of working surfaces)	dirty surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution or 5,0 g/l Sodium dodecyl sulphate (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection with mechanical action (e.g. wiping of working surfaces)	clean surfaces room temperature 5 min to 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
crate washers (crates, boxes, buckets, tablets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/l bovine albumin solution or 5,0 g/l Sodium dodecyl sulphate (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/l bovine albumine solution or 5,0 g/l Sodium dodecyl sulphate (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/l bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min

4.5.3 Overview of the standards relevant in food, industrial, domestic and institutional areas and their main features

Table 20 — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods for bactericidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time min	Interfering substances	Logarithmic reduction expressed in lg
EN 1276 2,1	Obligatory test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	20	5 (1 for hand disinfection)	Clean conditions: bovine albumin: 0,3 g/l and/or Dirty conditions: bovine albumin: 3,0 g/l	≥ 5,0
	The following additional test conditions are permitted:				
	Salmonella enterica subsp. *enterica*, Serotype *typhimurium* ATCC 13311*Lactobacillus brevis* DSM 6235 *Enterobacter cloacae* DSM 6234 Other additional strains are permitted	4, 10, 30, 40	1 or 15 or 30 or 60	1 % reconstituted skimmed milk or 10,0 g/l yeast extract or 10,0 g/l sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/l Sodium dodecyl sulphate	≥ 5,0

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 13697 2,2	Obligatory test conditions				
	Pseudomonas aeruginosa ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	18 to 25	5	**<u>Clean conditions:</u>** Skim milk: 8,5 g/l (only for *Pseudomonas aeruginosa*) bovine albumin: 0,3 g/l (other 3 strains) and/or <u>Dirty conditions:</u> bovine albumin: 3,0 g/l	≥ 4,0
	The following additional test conditions are permitted:				
	Salmonella enterica subsp. *enterica*, Serotype *typhimurium* ATCC 13311 *Lactobacillus brevis* DSM 6235 *Enterobacter cloacae* DSM 6234 Other additional strains are permitted	4 or 10 or 40	1 or 15 or 30 or 60	1 % reconstituted skimmed milk or 10,0 g/l yeast extract or 10,0 g/l sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/l Sodium dodecyl sulphate	≥ 4,0

Table 21 — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods for fungicidal and yeasticidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time min	Interfering substances	Logarithmic reduction expressed in lg
EN 1650 2,1	Obligatory test conditions				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus niger*[a] ATCC 16404	20	15	Clean conditions: bovine albumin: 0,3 g/l and/or Dirty conditions: bovine albumin: 3,0 g/l	≥ 4,0
	The following additional test conditions are permitted:				
	Saccharomyces cerevisiae ATCC 9763 *Saccharomyces cerevisiae* DSM 70487 var. *diastaticus* Additional strains are permitted	4 or 10 or 40	1 or 5 or 30 or 60	1 % reconstituted skimmed milk or 10,0 g/l yeast extract or 10,0 g/l sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/l Sodium dodecyl sulphate	

EN reference **Phase, step**	**Test organisms**	**Temperature** °C	**Contact time** min	**Interfering substances**	**Logarithmic reduction** expressed in lg
EN 13697 2,2	Obligatory test conditions				
	yeasticidal activity: only *Candida albicans* ATCC 10231 or **fungicidal activity:** *Candida albicans* ATCC 10231 **and** *Aspergillus brasiliensis*[b] ATCC 16404	18 to 25	15	Clean conditions: bovine albumin: 0,3 g/l and/or Dirty conditions: bovine albumin: 3,0 g/l	≥ 3,0
	The following additional test conditions are permitted:				
	Saccharomyces cerevisiae ATCC 9763 *Saccharomyces cerevisiae* DSM 70487 var. diastaticus Additional strains are permitted	4 10 40	1 5 30 60	1 % reconstituted skimmed milk or 10,0 g/l yeast extract or 10,0 g/l sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/l Sodium dodecyl sulphate	≥ 3,0

a The name of "*Aspergillus niger* ATCC 16404" has been changed to "*Aspergillus brasiliensis* ATCC 16404".

b Formerly known as "*Aspergillus niger* ATCC 16404".

Table 22 — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods for phagocidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time min	Interfering substances	Logarithmic reduction expressed in lg
EN 13610 2,1	Obligatory test conditions				
	Bacteriophage P001 DSM 4262 Bacteriophage P008 DSM 10567	20	15	1 % acidic whey	≥ 4,0
	The following additional test conditions are permitted:				
		4 or 10 or 40	5 or 30 or 60	1 % reconstituted skimmed milk	≥ 4,0

Table 23 — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods for sporicidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time min	Interfering substances	Logarithmic reduction expressed in lg
EN 13704 2,1	Obligatory test conditions				
	Spores of *Bacillus subtilis* ATCC 6633	between 4 and 75	between 1 and 60	Clean conditions: bovine albumin: 0,3 g/l and/or Dirty conditions: bovine albumin: 3,0 g/l	≥ 3,0
	The following additional test conditions are permitted:				
	Spores of *Bacillus cereus* ATCC 12826 Spores of *Clostridium sporogenes 51* CIP 7 939	between 4 and 75	between 1 and 60	1 % reconstituted skimmed milk	≥ 3,0

5 Precision of the test methods (Repetitions)

With many of the test methods of CEN/TC 216 ring trials have been performed to determine their feasibility and to evaluate their precision. The results and the statistical analyses of the ring trials are summarized in each of those standards, including ensuing recommendations. The current precision of the standards is within acceptable tolerance. Pass criteria in the standards consider the imprecision of the test methods, and thus meeting the pass criteria would allow for a positive evaluation of the product without any further need for evaluation of imprecision. However, within the culture of best practice, the following advice should lead to improved precision.

a) The testing laboratory has to be compliant with an adequate quality assurance system (e.g. EN ISO/IEC 17025) which includes proficiency testing and the regular participation at ring trials where available.

b) Strongly recommended options for further improvement are repetitions of the test and/or the inclusion of an internal standard and/or performing the test in a second and/or third laboratory. When doing the latter the second laboratory (and any further laboratory) might only repeat the test which is regarded as the most relevant one with the least susceptible test organism(s). If results from two or more laboratories are used, each laboratory has to specify one result, e.g. "R = > 5,23 lg (EN 13727-instrument disinfection)". Then the mean of the results of all laboratories is calculated assuming each laboratory's result as equivalent. Results with lg reduction "more than" are set as this figure, e.g. "> 5,23 lg" is used for calculation as "5,23 lg". All lg values are converted to real numbers, e.g. 5,23 lg to about 170 000. The mean is the arithmetic mean of these converted numbers. The lg of this arithmetic mean is the mean lg reduction. If one of the testing laboratories obtains a result less than the required lg reduction the product shall pass if further tests by three other laboratories demonstrate a pass. The calculations above cannot be done with tests where pass criteria are not expressed as lg reduction (for example hygienic handrub).

c) In case of repetition of the test it is unnecessary to repeat the test with all test-organisms but only with the least susceptible to the product under test.

d) If two or more tests are carried out to support a claim of performance (e.g. phase 2, step 1 and phase 2, step 2) and the ensuing recommendation for use, the tests may be ranked according to their order of relevance, i.e. their ability to predict the product's performance under real life conditions. In case of a ranking only the result of the most relevant test may be repeated taking into account advice b). If a ranking is not possible only the results of the test showing the highest minimum active concentration should be repeated.

The reduction of the number of test organisms caused by a product is generally expressed as decimal logarithm (lg) with two decimal places.

6 Proficiency testing

It is advisable to establish an instrument to measure the proficiency of the laboratory staff and to verify that the laboratory, under standard conditions, produces consistent results which comply with the specifications of the proficiency tests. This is often included within a laboratory quality assurance system. A proficiency test consists of performing the phase 2, step 1 and/or phase 2, step 2 tests with certain established reference substances (active substances or products) at certain established concentrations.

The proficiency test is a tool for the laboratory to ensure that the whole internal processes (including strain preservation, internal procedures, qualification of the personnel, etc.) are well implemented and kept under control through periodic quality control checks.

The proficiency test should be performed periodically (at least once per year), and it should be considered part of the quality control system.

7 Minimum information for the user including labelling regarding efficacy claims and use recommendations

The manufacturer shall provide at least the following information:

a) the type and/or purpose of the product (hygienic handwash, chemical disinfectant for surfaces etc.);

b) the area and field of application:

1) the area of application (medical, veterinary etc.);

the field of application (hygienic handrub, hard surfaces etc.);

c) the spectrum of activity (e.g. bactericidal, fungicidal); a general “microbicidal activity” cannot be claimed; any static activity like “bacteriostatic”, “fungistatic” (see 3.2.5) cannot be claimed;

d) reference of the European Standards to which conformity is claimed (e.g. bactericidal (EN xx), fungicidal (EN xx));

e) the recommended method(s) of application (use concentration(s), product diluent(s), volume to be applied, application procedure, contact time(s), temperature(s));

products tested without mechanical action need to state in the use instruction of the product that mechanical action e.g. wiping shall not take place during the contact time;

so far no test in WG 3 is available, in accordance with 4.2.5 the tests in line with 4.3.2.2 and 4.3.2.4 could be used;

f) conditions of soiling as defined in 3.3.10; state if pre-cleaning is required before disinfection.

8 Changes in European Standards

8.1 Revision of European Standards

When a standard listed in Clause 2 is revised and a new edition published, it shall be used for new products or new claims for existing products. Its Foreword shall state the changes made. If no technical changes have been made it shall be stated that data obtained from the previous version are still valid.

If technical changes have been made that might impact on the results obtained when using the former version it shall be stated in the European Foreword which tests using the new version shall be performed. For example, it may not be necessary to repeat all previous tests if changes refer to test conditions not affected by the technical changes in the revised version. The following alternative statements shall be included in the European Foreword of each revised standard:

a) The changes mentioned above have no impact on the test results obtained with reference to the previous version. Those results are still valid.

   or

b) The changes mentioned above have an impact on a part of the test results obtained with reference to the previous version. To conform to this new version the part(s):…….. ((has/have to be followed.)). If those results have been added the complete data set is regarded as valid.

   or

c) The changes mentioned above have an impact on the test results obtained with reference to the previous version. Products have to conform to this new version in order to support the claims for the activity corresponding to this European Standard.

The above mentioned tests using the new version shall be carried out within 18 months after publication of the new version as European Standard (prEN standards are not regarded as new versions). The publication date of the European Standard is indicated in the National Standards. After these 18 months, claims with reference to the previous are only allowed when there were no technical changes.

Changes in EN 14885 and EN 12353 should be adopted as soon as possible, but no later than 18 months after publication.

8.2 Impact of changes of EN 14885 on other European Standards

If EN 14885 is changed based on decisions of WG 1, WG 2 and WG 3 with regards to

a) the interpretation of test results/ conclusion and the prerequisites for recommendations for use;

b) the specification which standards have at least to be passed for a defined claim;

c) the accepted level of precision of the test methods;

d) the quality control for testing laboratories, and

e) terms and definitions.

these changes shall be directly and immediately applied to all concerned standards, until they have been incorporated into the standards, e.g. at their next revision. In the case of a) and b) the respective working group has to agree with these changes.

Nevertheless, the requirements shown in the Tables 1 to 23 shall be taken from the single standards and shall be decided by the working groups.

Annex A
(informative)

Recommendations on the use of terms and definitions in the area of disinfection and antisepsis

There are many terms which are used in the field of disinfection and antisepsis which may be confusing because these terms may have different meanings in different languages and countries.

Chemical disinfectants and antiseptics are used to produce a state in which the number of living/viable microorganisms has been reduced to a level which:

a) is appropriate to the practical situation, e.g. a level low enough to limit the release of microorganisms in numbers which could cause transmission of infection or disease and/or could cause the deterioration of perishable goods;

b) is not necessarily sterile, i.e. free from all microorganisms including viruses.

At the present time there is no accepted definition to describe the state as defined in a) and b) above. The state is often referred to as "hygienic", but this term can also be applied to other situations, e.g. cleaning.

Where a product which kills or inactivates microorganisms by action on their structure or metabolism is used in combination with a process of removal (i.e. washing process) of microorganisms from a surface, the total reduction of living microorganisms achieved should be sufficient to limit their release from the surface in order to prevent the transmission of infection and/or the deterioration of perishable goods under the conditions of intended application. Where this is achieved by application of a chemical product, that part of the process which involves inactivation of living microorganisms is referred to as "chemical disinfection".

The following are other definitions which do not appear in the text of the standards but are commonly used in relation to chemical disinfectants and antiseptics:

"Biocide" is an unspecific term applied to products related to the European "Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012" (BPR).

The terms "antibacterial, antifungal, antimicrobial, antiviral" may be used as common words (not as scientific terms). Since the mode of action is not precise, these terms cannot be used in a requirement for the activity or the efficacy of a product.

"Decontaminant/decontamination" are terms which are frequently used where radioactive substances have to be removed from organisms or items, and may be used where contaminant microorganisms are removed from items, mechanically or by a biocide. Decontamination is not a synonym of disinfection.

The term "sanitizer/sanitization" is used in some countries. No clear definition exists, so this term should be avoided in the field of antiseptics and chemical disinfectants.

"Activity and efficacy" are both terms which relate to the effects provoked by the product (antiseptic or chemical disinfectant) or the active substance on microorganisms. Both have to be measured if they are in the objective of a standard. Presently, it is possible to measure the activity of a product on defined microorganisms in specified experimental conditions. But efficacy implies the application of the product in order to reduce the number of present microorganisms to a level acceptable for a particular use. Efficacy is the result of the use of a product according to a defined application. No suitable methods exist presently to demonstrate with accuracy the overall effect (= efficacy) of this application of a

product. In summary, it is possible to test a chemical disinfectant (= activity), but not to evaluate disinfection.

The terms “sterility, sterile, sterilization, sterilant” fall outside the scope of activity of CEN/TC 216. Even if a product or active substance has been tested successfully for the whole spectrum of activities, including sporicidal activity, it cannot be regarded as a sterilant.

Annex B
(informative)

Recommendations on claims of efficacy on the basis of activity tests

B.1 For any products which are included in the European "Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012" (BPR) [1], or any other relevant European directives or regulations for which specific efficacy is claimed, test data have to be approved by the regulatory authority and a product authorization obtained before the product can be marketed. In some cases, it may be judged that the models specified in the CEN/TC 216 standards are insufficient and/or inappropriate for the particular area of application.

B.2 Chemical disinfectants which are specifically intended by the manufacturer to be used for the disinfection of medical devices are medical devices and therefore these products, as well as conforming to the instrument, laundry or surface disinfection standards in Table 1, are required to carry a CE mark since they are subject to the European Directive 93/42/EEC [2], now replaced by Medical Device Regulation (MDR), Council Regulation 2017/745.

B.3 In selecting an appropriate testing scheme to support a claim of specific activity the following should be considered:

Where results of one phase and step are considered to provide sufficient information for the particular application, the other phase or phases may be omitted (e.g. in CIP application, no phase 2/step 2 test is required).

B.4 In defining a use dilution for the product and application the following should be considered:

When the product dilution required to pass one phase or step is significantly higher than that required to pass the other phases or steps, the recommended use dilution should be chosen taking into account the intended use of the product in relation to the design of the tests. This can happen, for example where results from phase 2, step 1 and phase 2, step 2 tests are inconsistent with each other or with those of a valid field trial. In such a case tests which are as close as possible to the practical application should be preferred to recommend a use dilution for the product. Therefore, where infection prevention is not indicated, it may be justified to support a claim based on the more relevant test result (phase 2, step 1 or phase 2, step 2) even if it was not the hardest to pass.

E. g. products for automated cleaning and disinfection processes for certain items -, some standardized and validated test methods (international or national standards) are available as phase 3 test to evaluate the whole reprocessing procedure. In these cases, even the phase 3 tests can be regarded as close as possible to the application and the intended use of the product and data from such tests should be chosen for the recommendation of the use dilution.

B.5 In all situations as described above, the scientific or other justification for applying the scheme of testing or interpreting the results should be given.

B.6 When required by the regulations (see B.1), approval of claims is at the discretion of the relevant regulatory authority.

Annex C
(informative)

Phase 3 tests and other means of assessing efficacy

C.1 General

Phase 3 tests include both field tests under practical conditions and simulated use tests. These can be performed in addition to or instead of phase 2, step 1 and phase 2, step 2 tests. Additionally, historical use data can be used to assess the efficacy of a product and treatment regimes. Validated methodology for these types of test is not available, but may be developed in the future. This annex sets out guidance in the form of factors to be considered in the design of field trials and simulated use tests. This annex also provides guidance for use when determining the acceptability of data from sources other than standardized laboratory tests to support claims made for a chemical disinfectant or antiseptic. In the following only the term 'product' will be used.

A phase 3 test can be carried out in many different cases where a product is used. These include:

— disinfection of equipment in food, pharmaceutical or other processing plants by immersion, spraying, clean-in-place or other methods;

— disinfection of rooms, buildings, containers, transport vehicles and other enclosed spaces by spraying, mopping, vaporization or other methods;

— disinfection of catering utensils, medical equipment and other small items by immersion, washing and other processes;

— disinfection of kitchen, bathroom and other hard surfaces by spraying, mopping or other processes;

— disinfection of water systems by addition of a product, either routinely or as a shock treatment;

— disinfection of hands, tyres, boots, fabrics and other soft surfaces by washing, wiping, immersion or other processes;

— antiseptic procedures mainly in the medical and veterinary area.

This list is not exhaustive and the guidance in the annex can be applied and adapted as appropriate for individual circumstances.

C.2 Comparison with phase 2 tests

Phase 2 tests, both step 1 and step 2, have been developed to provide a defined set of laboratory conditions for the evaluation of the efficacy of products. These laboratory conditions simulate the actual use conditions such as contact time, temperature, soiling and site of use in a well standardized way to provide good reproducibility. Nevertheless, there are inevitable differences between the conditions used in a laboratory test and the actual conditions of use of a product. Furthermore, the efficacy necessary to meet the requirements of a standard describing a laboratory method for the evaluation of the efficacy of a product is only a representative estimate of the standard of antimicrobial performance required in practice.

In contrast, phase 3 tests, often described as field trials, can establish directly the performance of a product under more realistic conditions of use. These conditions are however likely to be specific to the

individual site of use and even to each individual occasion when the product is used, depending on not just the microbial challenge but the prevailing conditions under which the product is used. Hence a phase 3 test consists of a set of measurements so that the overall performance can be evaluated from a series of individual treatments.

Phase 3 tests typically assess performance against naturally occurring microorganisms under normal operating conditions, not against microorganisms that have been deliberately introduced and which may not be representative of the natural microflora. However, in some circumstances it may be advantageous to introduce a microbial challenge such as coupons or swatches contaminated with specific microorganisms. In such cases, the deliberate introduction of additional microorganisms shall be assessed carefully in advance of the test to ensure that safety is not compromised. Contaminated materials to be introduced into a system should be prepared following the methods described in any available and relevant phase 2 test.

C.3 Other means of assessing efficacy

The key feature of a phase 3 test is that it is carried out under typical operational conditions in a process in which a product is or may be used routinely, and that a series of measurements is taken according to a pre-determined plan to provide data that can be analysed statistically against defined criteria to demonstrate whether a product has the required antimicrobial performance.

The site or sites of the test are usually actual sites of use, although they could be pilot or prototype installations rather than full size facilities. It can nevertheless be quite difficult to read across data from one field trial to several related but different uses and carrying out a series of large field trials can be prohibitively expensive. Simulated use tests, where a development system can be used to investigate several types of use pattern may offer more robust data. In such cases the possibility of differences between pilot and full scale environments should be considered. Such differences can include, for example, effects only seen after a period of operation that has enabled a pilot plant to reach typical operational conditions of soiling, residues and temperature, or differences in the ratio of surface areas to liquid volumes. However, pilot plants can allow more conditions to be varied and more experimental treatments to be tested than when using full scale production facilities and can provide useful information about the efficacy of a product.

Other simulated use tests can take place in a small, well-controlled model system, such a test using a small group of human volunteers to assess a skin disinfectant or a rig system to assess a liquid or hard surface disinfection process. In such cases the primary purpose of the experimental design is to assess efficacy and not to replicate an actual process and such tests should be regarded as a form of phase 2, step 2 test and not as a phase 3 test. Some standards exist for such test methods and these should be followed where available. In the absence of standard for such methods, the principles for phase 3 tests provided in this annex may, when suitably adapted, provide guidance on the conduct of other forms of phase 2, step 2 tests.

Useful information on the efficacy of a product may also be available from the historical use of the product over an extended period of time. In many cases the product will have been used as a routine preventative treatment and the nature and extent of any microbial challenge will typically be unknown. However the suitability of the product to control microorganisms may be assessed from any available microbiological results, such as enumerations of the microbial content of a system or product or the absence or an acceptable number of relevant indicator organisms. The ability of the treatment to provide adequate microbial control can also be deduced from the absence of adverse effects such as infection, illness or spoilage. Such historical information, if capable of assessment and not merely opinion or subjective, can form part of a weight of evidence assessment in conjunction with a limited set of phase 2, step 1 and/or phase 2, step 2 tests.

C.4 Requirement for a phase 3 test

A phase 3 test, typically requires extensive resources and the use of a new product during a field trial can potentially result in unacceptable performance of a process that, prior to the test, was operating successfully. Phase 3 tests are therefore only to be performed where there are clear advantages in having such data. Appropriate phase 2 tests would usually be sufficient to demonstrate adequate efficacy for commercial or product authorization purposes and phase 3 test data would not normally be required. This is especially the case where a product is established and has a history of demonstrated acceptable efficacy, or where the underlying technology is well known and tested.

Phase 3 tests may however usefully be undertaken in other circumstances. For example, a novel technology may lack both historic data to support claims of efficacy and suitable standardized laboratory methods for the evaluation of efficacy. In other cases, the users or operators of a specific facility or type of equipment may wish to conduct a phase 3 test to provide a robust data package to establish the efficacy of a product under their particular circumstances. Conversely, the manufacturer of a product with widespread use, such as a consumer product, may wish to conduct a phase 3 test to confirm the operational conditions under which the product has the required efficacy.

C.5 Safety

Before any phase 3 testing is carried out it is necessary to identify and comply with any local legal requirements, such as those governing research and development activities with new products.

Potential risks should be identified and suitable risk management measures implemented to ensure that the field trial will not give rise to any unacceptable risks. Possible risks to humans, animals, equipment, products and the environment arising from the use of the product in a field trial should be identified and assessed. Toxicological and chemical risks to operators, users, bystanders and through residues in, for example, food and the environment, should be considered and documented. Potential consequences of any failure by the tested product to provide adequate control of microorganisms could include not just the risk of infection, but also product spoilage and the shutdown of plant for remedial treatment. A full size phase 3 test should not be undertaken unless the product has been shown to be effective using relevant laboratory efficacy test methods.

In addition to this risk assessment, procedures for monitoring to ensure no unacceptable risks occur and to control any problems arising during the trial period should be defined and documented in advance of any testing of the product. Furthermore, the criteria for intervention or stopping the trial shall be defined, documented and agreed by all concerned parties prior to commencement of the trial. Responsibilities and authority for decision making and any for any consequential losses or corrective actions should similarly be agreed before a field trial commences.

A phase 3 test should be performed following the label instructions and other guidance on the use of the product, including any pre-treatment or ancillary treatments that are required or advised by the use instructions. The effects of any related pre-treatment or ancillary processes on the results of the phase 3 test should be considered.

C.6 Design of a phase 3 test

Products and uses are diverse and each phase 3 test is likely to have specific design features. The conditions of use will vary considerably according to the intended purpose of the product. The test design and success criteria should be agreed with all relevant stakeholders before commencing a phase 3 test.

Since the levels of contamination or challenge in a phase 3 test is often unknown, variable and may be low, the numbers of microorganisms recovered in the samples may also be low. Hence in assessing whether or not a product demonstrates adequate efficacy the guidance in this annex should be followed. In general, no specific numerical reduction of the number of microorganisms is required in a phase 3 test; instead the product is required to perform according to the appropriate definition in Clause 3 of this standard. For example, a chemical disinfectant should reduce the number of microorganisms in or on an inanimate matrix, by irreversible action on their structure or metabolism, to a level judged to be appropriate for the defined purpose.

The test facility should be selected to be representative and provide a typical but real challenge to the successful use of a product. It is generally not possible to incorporate an untreated control system into a field trial and so the performance of the product under evaluation would normally be compared to a different but relevant treatment.

Where a single test site is used, the product being tested should be compared with an established product under similar circumstances, usually by alternating the use of each product. For example, equipment could be disinfected with an established product for 2 weeks, and then with the product under test for 2 weeks. This process would then be repeated to give a total of 4 weeks with each product. Otherwise, separate but identical or very similar facilities can be tested in parallel using the product under evaluation and, as a comparative standard, an established product with a successful history of use in that facility. Where multiple, small scale use sites are used for an evaluation, they should be selected to be representative and allocated to the test and reference products to ensure statistical randomness. Statistical methods would normally be used in the design of a phase 3 test to establish in advance that the data generated in the test would be suitable for meaningful analysis.

The purpose of the phase 3 test is to demonstrate the efficacy of the product or disinfection process under actual use conditions. The test should be carried out for an adequate period to allow the product to be evaluated over a range of circumstances. If a product is used on a daily basis or more frequently, the duration of the test may be two months. If a product is used less frequently, the overall duration of the test is typically longer to allow for an adequate number of treatments for useful statistical evaluation. The test design should include consideration of the means, quantity, rate and timing of the dosing application and the times of sampling relative to the time(s) of dosing.

The test design should consider external and uncontrolled factors which may influence the challenges on a disinfection regime such as temperature, weather and organic and soil loading on the system, which in turn may vary according to season and between weekends and weekdays. The frequency of sampling should also be designed to provide sufficient data points over a range of circumstances while keeping the overall number of samples to be processed at a manageable level. The design should provide a set of data that would be expected to show clearly whether or not a product was sufficiently efficacious under field conditions according to predetermined criteria.

Relevant microorganisms should be selected for enumeration and a sampling protocol established. Samples should be taken not only at easily treated locations but also at places where microorganisms are likely to be found, such as in corners of equipment. Samples should be taken at representative intervals. These typically include not only after the disinfection process but, when appropriate in a periodic disinfection process, before and after any cleaning to give an indication of the challenge that the product experienced during the test period. Sampling procedures should enable acceptable recovery of viable microorganisms.

The technical procedures to enumerate microorganisms should be described. Factors to consider include neutralization and verification of the neutralization procedure, recovery of damaged but viable organisms, the appropriate culture media and incubation conditions, the number of replicates, accepted limits for counting and the interpretation of results.

In some industrial or other processes, existing measurement systems, including analyses of a final product, may be used, but supplemental testing is also likely to be needed to provide a more comprehensive assessment of the efficacy of a product. Consideration should also be given to other non-biological measures of successful disinfection, such as solution pH or turbidity. Preference should be given to objective criteria but subjective assessments such as odour or aesthetic quality may be included in the evaluation if these are important criteria for judging the suitability of a disinfection regime.

In some cases, such as evaluation of a consumer product, it may be possible for users to be unaware of the actual product being used, provided that adequate safety and use information is made available. Such blind trials can eliminate or decrease any human factors that could give a bias to any results. Nevertheless, it should be recognized that users, especially non-professional users, may apply a product slightly differently or more conscientiously when aware of a trial than under other circumstances. The robustness of any treatment to minor misuse should be considered when designing and evaluating a phase 3 test.

C.7 Performance of a phase 3 test

A preliminary meeting with all those involved in the test should be carried out to ensure that all of those engaged in the trial fully understand their roles and responsibilities.

Unless specified otherwise as part of the complete process, cleaning and other procedures ancillary to disinfection should be conducted in an identical fashion for all products used throughout the test.

Samples should be collected and measurements taken by suitably trained or informed personnel. Ideally, all similar samples should be taken by the same personnel throughout the trial to ensure consistency. All samples should be adequately labelled so that there is no confusion or uncertainty. It is advantageous to check periodically that sample numbering matches the appropriate sample site and to monitor the sampling process to ensure that the correct procedures are being followed.

Samples should be taken, transported, stored and analysed following generally accepted microbiological or chemical practices by suitably qualified and trained personnel.

All sampling and related equipment and materials should be stored appropriately and carefully packed away after use, ensuring that no debris is left at the sample site. It is good practice to carry out sterility and other control checks during the test to assist in identifying any anomalous results due to contaminated equipment or other process failures.

Any unusual or non-routine events that may have an impact on the results of the trials should be recorded as they occur. Similarly, any deviations from the test protocol should be recorded.

C.8 Results of a phase 3 test

Upon completion of the sampling and enumeration stages of a phase 3 test, statistical comparison between the efficacy of the product under evaluation and the standard product would normally be undertaken using Student's *t*-test. Unless other criteria were established during the test design, the test product shall be shown to be at least as effective as the proven established product at the test site for the measured parameters, that is not significantly less effective than the proven existing product ($P < 0,05$).

In reporting the results of a phase 3 test, the test protocol should be included, giving the agreed features and methodology incorporated into the trial design. Any deviations from the protocol should be

reported. All results obtained should be included in an appendix, with identification and explanation of any data points that have been excluded from the analysis of the results. The conclusions from the test should be clearly stated.

Annex D
(normative)

Differentiation of active and non-active substances in a product

D.1 General

When applying for authorization of a chemical disinfectant or antiseptic the applicant provides a composition statement in which one or more active substances and/or one or more co-formulant(s) are identified. In some cases the Competent Authority (e.g. for biocidal products, medical devices or drugs) might regard one or more of the co-formulants as additional active substance(s). In some cases an explanation can be given and accepted. In cases where this is insufficient, tests can be performed to demonstrate the "non-activity" of the co-formulant(s).

D.2 Test Strategy

Three kinds of tests have been identified (see D.3). The applicant may choose one, two or all of them – as necessary and appropriate.

Each test should be performed as a phase 2, step 1 test under the test conditions (test organism, interfering substance/soiling, contact time, concentration of the product) used for a product claim. Product claim means for example: "bactericidal activity: 1,5 %, 3 min, dirty conditions." For the purpose of the differentiation of active and non-active substances results from phase 2, step 2 tests should be ignored even if they require a higher product-concentration for the claim.

In all tests the pH of the formulation under test should be adjusted to the pH of the microbicidal product.

For all tests it is requested to show a definite lg reduction considering the detection limits of the respective tests, i.e. within the detection limits precise lg reduction values need to be given such as 2,68 lg instead of < 5,00 or 2,25 lg instead of < 4,00 lg. The EN tests may be adapted accordingly, if necessary. For instance extra dilution steps might be needed for these tests to show lg reductions around 3,00 and 3,50.

These tests should generally be performed using bacteria (including mycobacteria and bacterial spores) as test organisms. If other test organisms are used to demonstrate non-activity only those that are claimed for the product are allowed.

D.3 Description of the tests

Test 1: The product without active substance is tested.

The active substance(s) are replaced by water or any other suitable substance(s). If the active substance(s) cannot be replaced for whatever reason, the concentration of the product without active substance has to be decreased accordingly. Example: Amount of the active substances is 30 g/100 g in the microbicidal product. Concentration used for claiming bactericidal activity is 2,0 %. Concentration in Test 1 should be 2,0 % of 70 % of the product (i.e. 70 g/100 g) = 1,4 %.

Test 2: Each co-formulant under question is tested alone.

The concentration (of the co-formulant) in the test has to be adapted to the relative amount of the co-formulant in the microbicidal product. Example: Amount of the co-formulant is 3 g/100 g in the microbicidal product. Concentration used for claiming bactericidal activity is 3,0 %, concentration of the co-formulant in Test 2 should be 3,0 % of 3,0 % of the product (i.e. 3 g/100 g) = 0,09 %.

Test 3: The product without the co-formulant is tested.

Two products are tested in parallel: the microbicidal product and the same product, but without the co-formulant that should be replaced by water or any other suitable substance(s). Separate testing may be performed for each co-formulant under question removing only one co-formulant at a time.

D.4 Interpretation of test results

To demonstrate in tests 1 and 2, that the co-formulants under question are not active substances the lg reduction should be at least 2,00 lg lower than the lg reduction required to pass the EN standard performed. For test 3, the lg reduction of the two products should be similar, i.e. show no more than 1,50 lg difference.

Three examples shall illustrate this evaluation:

Test 1: The full product demonstrates a 5,00 lg bactericidal activity. If the product without active substance demonstrates a ≤ 3,00 lg inactivation, all co-formulants are not active ingredients.

Test 2: The full product demonstrates a 4,00 lg mycobactericidal activity. If the co-formulant under question alone demonstrates a ≤ 2,00 lg mycobactericidal inactivation, it is not an active ingredient.

Test 3: The full product demonstrates a 4,00 lg fungicidal activity. If the product without the co-formulant under question demonstrates a fungicidal inactivation of ≤ 2,50 lg, the co-formulant under question is an active ingredient.

In cases where more than one co-formulant is under question and test 1 shows low lg reduction, none of these co-formulants can be regarded as an active substance. However, if in this test 1 a high lg reduction is seen, further tests 2 and/or 3 with each co-formulant under question would be required to verify which co-formulant is causing this effect.

Annex E
(informative)

Choice of meaningful concentrations when testing products according to the standards

The “middle” concentration out of the three obligatory concentrations to be tested should always demonstrate a minimum lg reduction of 1 and a maximum of 1 lg less than the required “pass” lg reduction.

EXAMPLE *Aspergillus brasiliensis* pass criterion: 4 lg reduction. The highest concentration should demonstrate 4 lg reduction or more, the middle one between 1 lg and 3 lg reduction and the lowest one any non-active reduction.

NOTE 1 Hygienic and surgical handrub and handwash products (phase 2, step 2) are excepted from this exercise as it is too burdensome to test different concentrations with volunteers.

NOTE 2 The same applies for products for airborne disinfection as the tests are too burdensome to be performed.

Annex F
(informative)

CEN/TC 216 standards in preparation or under revision

F.1Medical area

prEN 13623 **rev.**: 2018-04, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems — Test method and requirements (phase 2, step 1)*

prEN 13624 **rev**.:2019-08, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1)*

prEN 17387:2019-05, *Chemical disinfectants and antiseptics — Quantitative non-porous surface test for the evaluation of bactericidal and/or yeasticidal and/or fungicidal activity of chemical disinfectants used in medical area — Test method and requirements without mechanical action (phase 2, step 2)*

prEN 17430: 2019-08, *Chemical disinfectants and antiseptics — Hygienic handrub virucidal — Test method and requirements (phase 2, step 2)*

F.2Veterinary area

prEN 17422:2019-07, *Chemical disinfectants and antiseptics — Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area — Test method and requirements (phase 2, step 2)*

F.3Food, industrial, domestic and institutional areas

REGIST-Project: WI 00126119, *Quantitative surface test for the evaluation of residual antimicrobial (bactericidal and/or yeasticidal) efficacy of liquid chemical disinfectants on hard non-porous surfaces — Test method*

REGIST-Project: WI 00126122, *Chemical disinfectants and antiseptics — Quantitative test method for the evaluation of bactericidal, yeasticidal and fungicidal activities on non-porous surfaces with mechanical action employing wipes or mopes in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 2)*

REGIST-Project: WI 00126125, *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)*

REGIST-Project: WI 00126126, *Chemical disinfectants and antiseptics — Quantitative carrier test method for the evaluation of sporicidal activity of chemical disinfectants on hard non-porous surfaces in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 2)*

REGIST-Project: WI 00126127, *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)*

F.4Others

prEN 12353: 2019-01, *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 **rev.**, *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

prEN 17272: 2018-08, *Chemical disinfectants and antiseptics — Quantitative carrier test for airborne room disinfection by automated processes — Determination of bactericidal, fungicidal, yeasticidal, sporicidal, tuberculocidal, mycobactericidal, virucidal and phagocidal activities in the medical area, veterinary area and food, industrial, domestic and institutional areas — Test methods and requirements (phase 2, step 2)*

REGIST-Project: WI 00216106, *Chemical Disinfectants and Antiseptics — Quantitative Carrier test for Airborne Room Disinfection by Manual Processes - Determination of Bactericidal, Fungicidal, Yeasticidal, Sporicidal, Tuberculocidal, Mycobactericidal, Virucidal and Phagocidal Activities in the Medical Area, Veterinary Area and Food, Industrial, Domestic and Institutional Areas — Test Methods and Requirements Phase 2, Step2*

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ISO EN 9000, *2015-11,* Quality management systems — Fundamentals and vocabulary

EN ISO 17025, *General requirements for the competence of testing and calibration laboratories*

Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012 (BPR)

Council directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001

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