NAMS 13624:2024

First Edition

EN 13624:2021

NAMIBIAN STANDARD

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)

This Namibian standard is the identical adoption of EN 13624:2021 and is adopted with the permission of the European Committee for Standardization

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NAMIBIAN STANDARDS INSTITUTION

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National foreword

This Namibian Standard (NAMS) is identical to EN 13624:2021, and was approved for adoptions by the Namibian Standards Institution CEO.

Namibian standards are developed based on NSI Standards development procedures in accordance with the rules given in the International Organisation for Standardisation/ International Electrotechnical Commission (ISO/IEC) Directives 1, ISO/IEC Guide 21-1 Adoption of international standards as regional or national standards and WTO – TBT World Trade Organisation code of Good Practice (which is published as Annex 3 in the TBT Agreement)

The NSI Technical Committee responsible for this standard is NSI TC 14, Chemicals.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

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)

Désinfectants chimiques et antiseptiques - Essai quantitatif de suspension pour l'évaluation de l'activité fongicide ou levuricide en médecine - Méthode d'essai et exigences (phase 2, étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der fungiziden oder levuroziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 3 October 2021.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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European foreword

This document (EN 13624:2021) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2022, and conflicting national standards shall be withdrawn at the latest by May 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13624:2013.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other tests of CEN/TC 216 existing or in preparation and to improve the readability of the standard and thereby make it more understandable. The following is a list of significant technical changes since the last edition:

— De-harmonization of the standard (Annex ZA and references to MDR/MDD deleted);

— Textile disinfection was added (see Table 1, 5.5.1.3);

— The amounts for the dirty conditions for the modified method for ready-to-use products were reduced (5.2.2.8.4 b));

— Clarification that a neutralization time of 10 s shall be used for all products with contact times of 10 min or shorter (5.5.2.2. c) and 5.5.2.5 b));

— Explanation for alternative controls for chemo-thermal disinfection (5.5.2.3);

— The reference to CIP numbers for the fungi strains were deleted and the UMIP numbers were added (Annex A);

— Harmonization of the text with EN 13727;

— Correction of editorial mistakes.

The changes of this revision have no impact on the test results obtained with reference to the version EN 13624:2013. Those results are still valid.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document specifies a suspension test for establishing whether a chemical disinfectant or an antiseptic has a fungicidal or yeasticidal activity in the area and fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which can influence its action in practical situations. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.