

**Cosmetics - Microbiology - Detection of *Candida albicans*
(ISO 18416:2015, Corrected version 2016-12-15 +
ISO 18416:2015/Amd 1:2022)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18416:2015+A1:2022 sisaldab Euroopa standardi EN ISO 18416:2015 ja selle muudatuse A1:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18416:2015+A1:2022 consists of the English text of the European standard EN ISO 18416:2015 and its amendment A1:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.12.2015, muudatus A1 12.10.2022.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 16.12.2015, for A1 12.10.2022.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega A1 A1 . Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags A1 A1 . The standard is available from the Estonian Centre for Standardisation and Accreditation.

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English Version

**Cosmetics - Microbiology - Detection of Candida albicans
(ISO 18416:2015, Corrected version 2016-12-15 + ISO
18416:2015/Amd 1:2022)**

Cosmétiques - Microbiologie - Détection de Candida
albicans (ISO 18416:2015, Version corrigée 2016-12-
15 + ISO 18416:2015/Amd 1:2022)

Kosmetische Mittel - Mikrobiologie - Nachweis von
Candida albicans (ISO 18416:2015, korrigierte Fassung
2016-12-15 + ISO 18416:2015/Amd 1:2022)

This European Standard was approved by CEN on 26 September 2015. Amendment A1 was approved by CEN on 17 September 2022.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 18416:2015) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 "Cosmetics" 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 juin 2016, and conflicting national standards shall be withdrawn at the latest by juin 2016.

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Endorsement notice

The text of ISO 18416:2015, Corrected version 2016-12-15 has been approved by CEN as EN ISO 18416:2015 without any modification.

A1 Amendment A1 European foreword

This document (EN ISO 18416:2015/A1:2022) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by AFNOR.

This Amendment to the European Standard EN ISO 18416:2015 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2023, and conflicting national standards shall be withdrawn at the latest by April 2023.

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Endorsement notice

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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The committee responsible for this document is ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 18416:2007), of which it constitutes a minor revision.

A1 Amendment A1 foreword

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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 392, *Cosmetics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html. **A1**

Introduction

Microbiological examinations of cosmetic products are carried out according to an appropriate microbiological risk analysis in order to ensure their quality and safety for consumers.

Microbiological risk analysis depends on several parameters such as the following:

- potential alteration of cosmetic products;
- pathogenicity of microorganisms;
- site of application of the cosmetic product (hair, skin, eyes, mucous membranes);
- type of users (adults, children under 3 years).

For cosmetics and other topical products, the detection of skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant because they can cause skin or eye infections. The detection of other kinds of microorganism might be of interest since these microorganisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during the manufacturing process.

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Cosmetics — Microbiology — Detection of *Candida albicans*

1 Scope

This International Standard gives general guidelines for the detection and identification of the specified microorganism *Candida albicans* in cosmetic products. Microorganisms considered as specified in this International Standard might differ from country to country according to national practices or regulations.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis to determine the types of cosmetic product to which this International Standard is applicable. Products considered to present a low microbiological (see ISO 29621) risk include those with low water activity, hydro-alcoholic products, extreme pH values, etc.

The method described in this International Standard is based on the detection of *Candida albicans* in a non-selective liquid medium (enrichment broth), followed by isolation on a selective agar medium. Other methods may be appropriate dependent on the level of detection required.

NOTE For the detection of *Candida albicans*, subcultures can be performed on non-selective culture media followed by suitable identification steps (e.g. using identification kits).

Because of the large variety of cosmetic products within this field of application, this method may not be appropriate in every detail for some products (e.g. certain water immiscible products). Other International Standards (ISO 18415) may be appropriate. Other methods (e.g. automated) may be substituted for the tests presented here provided that their equivalence has been demonstrated or the method has been otherwise shown to be suitable.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21148:2005, *Cosmetics — Microbiology — General instructions for microbiological examination*

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*

3 Terms and definitions

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

3.1

product

portion of an identified cosmetic product received in the laboratory for testing

3.2

sample

portion of the product (at least 1 g or 1 ml) that is used in the test to prepare the initial suspension