

**Cosmetics - Microbiology - Detection of Candida  
albicans**

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 18416:2009 sisaldab Euroopa standardi EN ISO 18416:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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ICS 07.100.99, 71.100.70

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ICS 07.100.99; 71.100.70

English Version

**Cosmetics - Microbiology - Detection of Candida albicans (ISO 18416:2007)**

Cosmétiques - Microbiologie - Détection de Candida albicans (ISO 18416:2007)

Kosmetik - Mikrobiologie - Nachweis von Candida albicans (ISO 18416:2007)

This European Standard was approved by CEN on 23 May 2009.

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## Foreword

The text of ISO 18416:2007 has been prepared by Technical Committee ISO/TC 217 “Cosmetics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 18416:2009 by Technical Committee CEN/SS H99 “Products for household and leisure use - Undetermined” the secretariat of which is held by CMC.

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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

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### Endorsement notice

The text of ISO 18416:2007 has been approved by CEN as a EN ISO 18416:2009 without any modification.

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## 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:

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

For cosmetics and other topical products, the detection of *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 those microorganisms (including indicators of faecal contamination, e.g. *Escherichia coli*) suggest hygienic failure during the manufacturing process.

# 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 so as to determine the types of cosmetic product to which this International Standard is applicable. Products considered to present a low microbiological risk include those with low water activity, hydro-alcoholic products, those with 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 might not be suited in every detail to some products (e.g. certain water-immiscible products). Other International Standards (e.g. ISO 18415) might be appropriate. Other methods (e.g. automated) can be substituted for the test presented here provided that their equivalence has been demonstrated or the method has been otherwise validated.

## 2 Normative references

The following referenced documents are indispensable for the application 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.

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, mycobactericidal, sporicidal and fungicidal 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