

Cosmetics - Microbiology - Detection of specified and nonspecified microorganisms (ISO 18415:2007)

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NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 18415:2011 sisaldab Euroopa standardi EN ISO 18415:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 30.06.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.06.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 18415:2011 consists of the English text of the European standard EN ISO 18415:2011.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 08.06.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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ICS 07.100.99, 71.100.70

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English Version

Cosmetics - Microbiology - Detection of specified and non-specified microorganisms (ISO 18415:2007)

Cosmétiques - Microbiologie - Détection des micro-organismes spécifiés et non spécifiés (ISO 18415:2007)

Kosmetik - Mikrobiologie - Nachweis von spezifizierten und nichtspezifizierten Mikroorganismen (ISO 18415:2007)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 18415:2007 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 18415:2011 by Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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Endorsement notice

The text of ISO 18415:2007 has been approved by CEN as a EN ISO 18415:2011 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 skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant because they can cause skin or eye infection. The detection of other kinds of microorganisms might be of interest since these microorganisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during manufacturing process.

Cosmetics — Microbiology — Detection of specified and non-specified microorganisms

1 Scope

This International Standard gives general guidelines for the detection and identification of specified microorganisms in cosmetic products as well as for the detection and identification of other kinds of aerobic mesophilic non-specified microorganisms in cosmetic products.

Microorganisms considered as specified in this International Standard might differ from country to country according to national practices or regulations. Most of them considered as specified microorganisms include one or more of the following species: *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Candida albicans*.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis in order 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, extreme pH values, etc.

The method described in this International Standard is based on the detection of microbial growth in a non-selective liquid medium (enrichment broth) suitable to detect microbial contamination, followed by isolation of microorganisms on non-selective agar media. Other methods can be appropriate depending on the level of detection required.

In this International Standard specific indications are given for identification of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Candida albicans*. Other microorganisms that grow under the conditions described in this International Standard, may be identified by using suitable tests according to a general scheme (see Annex A). Other standards (e.g., ISO 18416, ISO 21150, ISO 22717, ISO 22718) may be appropriate.

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 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*