

**Cosmetics - Microbiology - Detection of Escherichia coli
(ISO 21150:2015 + ISO 21150:2015/Amd 1:2022)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN ISO 21150:2015+A1:2022 sisaldab Euroopa standardi EN ISO 21150:2015 ja selle muudatuse A1:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21150:2015+A1:2022 consists of the English text of the European standard EN ISO 21150:2015 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, muudatused A1 28.09.2022.	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 28.09.2022.
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English Version

**Cosmetics - Microbiology - Detection of Escherichia coli
(ISO 21150:2015 + ISO 21150:2015/Amd 1:2022)**

Cosmétiques - Microbiologie - Détection d'Escherichia coli (ISO 21150:2015 + ISO 21150:2015/Amd 1:2022)

Kosmetische Mittel - Mikrobiologie - Nachweis von Escherichia coli (ISO 21150:2015 + ISO 21150:2015/Amd 1:2022)

This European Standard was approved by CEN on 26 September 2015. Amendment A1 was approved by CEN on 10 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 21150:2015) 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of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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Endorsement notice

The text of ISO 21150:2015 has been approved by CEN as EN ISO 21150:2015 without any modification.

A1 Amendment A1 European foreword

This document (EN ISO 21150:2015/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 21150:2015 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 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 21150:2006), which has been technically revised.

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 *Escherichia coli*

1 Scope

This International Standard gives general guidelines for the detection and identification of the specified microorganism *Escherichia coli* 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 products 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 *Escherichia coli* in a non-selective liquid medium (enrichment broth), followed by isolation on a selective agar medium. Other methods may be appropriate, depending on the level of detection required.

NOTE For the detection of *Escherichia coli*, 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 to some products in every detail (e.g. certain water-immiscible products). Other International Standards (ISO 18415) may 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 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