Cosmetics - Microbiology - Detection of specified and non-specified microorganisms (ISO 18415:2017 + ISO 18415:2017/Amd 1:2022)



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

| See Eesti standard EVS-EN ISO 18415:2017 +A1:2022 sisaldab Euroopa standardi EN ISO 18415:2017 ja selle muudatuse A1:2022 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 18415:2017+A1:2022 consists of the English text of the European standard EN ISO 18415:2017 and its amendment A1:2022. | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. | |
| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.06.2017, muudatus A1 28.09.2022. | Date of Availability of the European standard is 21.06.2017, for A1 28.09.2022. | |
| Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega 🗥 🛝 | The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A7] (A1]. | |
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ICS 07.100.40

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EUROPEAN STANDARD NORME EUROPÉENNE

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English Version

Cosmetics - Microbiology - Detection of specified and nonspecified microorganisms (ISO 18415:2017 + ISO 18415:2017/Amd 1:2022)

Cosmétiques - Microbiologie - Détection des microorganismes spécifiés et non spécifiés (ISO 18415:2017 + ISO 18415:2017/Amd 1:2022)

Kosmetische Mittel - Mikrobiologie - Nachweis von spezifizierten und nichtspezifizierten Mikroorganismen (ISO 18415:2017 + ISO 18415:2017/Amd 1:2022)

This European Standard was approved by CEN on 26 April 2017. Amendment A1 was approved by CEN on 9 September 2022.

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

European foreword

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This document (EN ISO 18415:2017/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 18415:2017 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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Contents Page

| | | nent A1 foreword 街 | | | |
|-------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--|--|
| | | nent A1 foreword (<u>A1</u> | | | |
| | | | | | |
| 1 | - | e | | | |
| 2 | Normative references | | | | |
| 3 | Terms and definitions | | | | |
| 4 | Principle | | | | |
| 5 | Dilue | ents and culture media | 4 | | |
| | 5.1 | General | 4 | | |
| | 5.2 | Diluent for the microbial suspension (tryptone sodium chloride solution) | 4 | | |
| | | 5.2.1 General | | | |
| | | 5.2.2 Composition | 4 | | |
| | | 5.2.3 Preparation | | | |
| | 5.3 | Culture media | 4 | | |
| | | 5.3.1 General | | | |
| | | 5.3.2 Enrichment broth | | | |
| | | 5.3.3 Non-selective agar medium | | | |
| 6 | Appa | aratus and glassware | 6 | | |
| | Strai | ns of microorganism | 6 | | |
| 7 | | | | | |
| | | | | | |
| 8 | Hand | lling of cosmetic products and laboratory samples | 7 | | |
| 8 | Hand Proc | dling of cosmetic products and laboratory samplesedure | 7 7 | | |
| 8 | Hand Proc 9.1 | dling of cosmetic products and laboratory samplesedure | 7 7 7 | | |
| 8 | Hand Proc | edureGeneral recommendations | 7 7 7 | | |
| 8 | Hand Proc 9.1 | dling of cosmetic products and laboratory samples edure General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General | 7 7 7 7 | | |
| 8 | Hand Proc 9.1 | dling of cosmetic products and laboratory samples edure | 7 7 7 7 | | |
| 8 | Hand Proc 9.1 | dling of cosmetic products and laboratory samples edure | 7 7 7 7 7 7 7 | | |
| 8 | Proc 9.1 9.2 | dling of cosmetic products and laboratory samples edure | 7 7 7 7 7 7 8 8 | | |
| 7 8 9 | Proc 9.1 9.2 | dling of cosmetic products and laboratory samples edure | 7 7 7 7 7 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 | dling of cosmetic products and laboratory samples edure | 7 7 7 7 7 7 8 8 8 | | |
| 8 | Proc 9.1 9.2 | dling of cosmetic products and laboratory samples edure General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos | 7 7 7 7 7 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining | 7 7 7 7 7 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test | 7 7 7 7 7 8 8 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | dure | 7 7 7 7 7 8 8 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test 9.5.3 Identification test Procedure for identification of the specified microorganism: Escherichia coli | 7 7 7 7 8 8 8 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test 9.5.3 Identification test Procedure for identification of the specified microorganism: Escherichia coli 9.6.1 Gram staining | 7 7 7 7 8 8 8 8 8 8 8 8 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 1. Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test 9.5.3 Identification test Procedure for identification of the specified microorganism: Escherichia coli 9.6.1 Gram staining 9.6.2 Oxidase test | 7 7 7 7 8 8 8 8 8 8 8 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test 9.5.3 Identification test Procedure for identification of the specified microorganism: Escherichia coli 9.6.1 Gram staining 9.6.2 Oxidase test 9.6.3 Identification test | 7 7 7 7 8 8 8 8 8 8 9 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | edure | 7 7 7 7 8 8 8 8 8 8 9 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | dling of cosmetic products and laboratory samples General recommendations Preparation of the initial suspension in the enrichment broth 9.2.1 General 9.2.2 Water-miscible products 9.2.3 Water-immiscible products 9.2.4 Filterable products Incubation of the initial suspension Isolation of specified and non-specified microorganisms Procedure for identification of the specified microorganism: Pseudomonas aeruginos 9.5.1 Gram staining 9.5.2 Oxidase test 9.5.3 Identification test Procedure for identification of the specified microorganism: Escherichia coli 9.6.1 Gram staining 9.6.2 Oxidase test 9.6.3 Identification test Procedure for identification of the specified microorganism: Staphylococcus aureus 9.7.1 Gram staining | 7 7 7 7 8 8 8 8 8 9 9 9 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | edure | 7 7 7 7 8 8 8 8 8 9 9 9 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | edure | 7 7 7 7 8 8 8 8 8 9 9 9 9 9 | | |
| 8 | 9.1 9.2 9.3 9.4 9.5 | edure | 7 7 7 7 8 8 8 8 8 9 9 9 9 9 | | |

| | | cedure for the identification of non-specified microorganisms | |
|-------|----------------------|--------------------------------------------------------------------------|----|
| | 9.9. | 0 | |
| | 9.9. | | |
| | 9.9. | | |
| | 9.9. | | |
| 10 | _ | of the results | |
| | | ection of specified microorganisms | |
| | | ection of non-specified microorganismsence of microorganisms | |
| | | | |
| 11 | | tion of the antimicrobial properties of the product | |
| | | paration of inoculumparation of inoculum | |
| | | cability of detection method by enrichment | |
| | | 3.1 Principle | |
| | | 3.2 Procedure | |
| | 11.3 | 3.3 Interpretation of suitability test results | 12 |
| 12 | Test repor | t | 12 |
| | = | ive) General scheme for identification of microorganisms | |
| | | | |
| Anne | x B (informat | ive) Other media | 14 |
| Anne | x C (informat | ive) Neutralizers of antimicrobial activity of preservatives and rinsing | g |
| | liquids | | 17 |
| Bibli | ography | | 18 |
| | | C, | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
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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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This document was prepared by Technical Committee ISO/TC 217, Cosmetics.

This second edition cancels and replaces the first edition (ISO 18415:2007), of which it constitutes a minor revision with the following changes:

- in the Scope, "see ISO 29621" has been added and the reference has been added to the Bibliography;
- in the Scope, "used" has been changed to "substituted" and "validated" has been changed to "shown to be suitable":
- in 3.8, the term "validated" has been changed to "demonstrated to be suitable";
- in Clause 4, the term "validated" has been changed to "demonstrated";
- in 5.1, "specifications" has been changed to "instructions";
- in 5.1, the phrase "are validated" has been changed to "have been demonstrated to be suitable";
- in 5.2.1, 5.3.3.1, 11.3.1, 11.3.2, instances of the term "validation" and in the heading title of 11.3.3 have been changed to "suitability test";
- in 11.3, the term "validation" in the heading title has been changed to "suitability";
- in 11.3.3, instances of "validated" have been changed to "satisfactory";
- in Clause 12 f), the term "validation" has been changed to "demonstration of the suitability".

An 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. (A)

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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 " O Provide Manager of the Control o failure during manufacturing process.

Cosmetics — Microbiology — Detection of specified and nonspecified microorganisms

1 Scope

This document 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 document 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 to determine the types of cosmetic products to which this document is applicable. Products considered to present a low microbiological risk (see ISO 29621) include those with low water activity, hydro-alcoholic products, extreme pH values, etc.

The method described in this document 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 document 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 document 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 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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.

 ${\tt ISO~21148:2017, Cosmetics-Microbiology-General\ instructions\ for\ microbiological\ examination}$

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