

**Cosmetics - Microbiology - Evaluation of the
antimicrobial protection of a cosmetic product
(ISO 11930:2019 + ISO 11930:2019/Amd 1:2022)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11930:2019+A1:2022 sisaldab Euroopa standardi EN ISO 11930:2019 ja selle muudatuse A1:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11930:2019+A1:2022 consists of the English text of the European standard EN ISO 11930:2019 and its amendment A1:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.02.2019, muudatus 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 13.02.2019, for A1 28.09.2022.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega $\boxed{A1}$ $\boxed{A1}$. 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 $\boxed{A1}$ $\boxed{A1}$. The standard is available from the Estonian Centre for Standardisation and Accreditation.

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English Version

**Cosmetics - Microbiology - Evaluation of the antimicrobial
protection of a cosmetic product (ISO 11930:2019 +
ISO 11930:2019/Amd 1:2022)**

Cosmétiques - Microbiologie - Évaluation de la
protection antimicrobienne d'un produit cosmétique
(ISO 11930:2019 + ISO 11930:2019/Amd 1:2022)

Kosmetische Mittel - Mikrobiologie - Bewertung des
antimikrobiellen Schutzes eines kosmetischen
Produktes (ISO 11930:2019 + ISO 11930:2019/Amd
1:2022)

This European Standard was approved by CEN on 27 December 2018. Amendment A1 was approved by CEN on 9 September 2022.

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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 11930:2019) 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 August 2019, and conflicting national standards shall be withdrawn at the latest by August 2019.

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This document supersedes EN ISO 11930:2012.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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Endorsement notice

The text of ISO 11930:2019 has been approved by CEN as EN ISO 11930:2019 without any modification.

A1 Amendment A1 European foreword

This document (EN ISO 11930:2019/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 11930:2019 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

The text of ISO 11930:2019/Amd 1:2022 has been approved by CEN as EN ISO 11930:2019/A1:2022 without any modification. **A1**

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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*.

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.

This second edition cancels and replaces the first edition (ISO 11930:2012), which has been technically revised. The main changes compared to the previous edition are as follows.

- Two types of diluents, composition 1 and composition 2 can be used as the diluents for bacteria and *Candida albicans* on the revised version (5.2.3).
- 5.6.2 Paragraph 2 has been changed to "When counts of surviving microorganisms obtained in 5.6.1.4 c) are less than 30 for bacteria and *C. albicans* or less than 15 for *A. brasiliensis* at the dilution where neutralization has been checked, record the number of colonies on Petri dishes and express results by multiplying by the dilution factor. If no colonies are observed at the dilution where neutralization has been checked, note the result as <1 and multiply by the dilution factor."

A1 Amendment A1 foreword

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Introduction

This document is designed to be used in the overall evaluation of the antimicrobial protection of a cosmetic product.

The antimicrobial protection of a product can come from many sources:

- chemical preservation;
- inherent characteristics of the formulation;
- package design;
- manufacturing process.

This document defines a series of steps to be taken when assessing the overall antimicrobial protection of a cosmetic product. A reference method for a preservation efficacy test (challenge test) along with evaluation criteria is also described in this document.

The test described in this document involves, for each test microorganism, placing the formulation in contact with a calibrated inoculum, and then measuring the changes in the microorganism count at set time intervals for a set period and at a set temperature.

The data generated by the risk assessment (see ISO 29621) or by the preservation efficacy test, or both, are used to establish the level of antimicrobial protection required to minimize user risk.

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Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

1 Scope

This document specifies a procedure for the interpretation of data generated by the preservation efficacy test or by the microbiological risk assessment, or both, when evaluating the overall antimicrobial protection of a cosmetic product.

It comprises:

- a preservation efficacy test;
- a procedure for evaluating the overall antimicrobial protection of a cosmetic product that is not considered low risk, based on a risk assessment described in ISO 29621.

The preservation efficacy test is a reference method to evaluate the preservation of a cosmetic formulation. It is applicable to cosmetic products in the marketplace.

This test does not apply to those cosmetic products for which the microbiological risk has been determined to be low according to Annex A and ISO 29621.

This test is primarily designed for water-soluble or water-miscible cosmetic products and can be used with modification to test products in which water is the internal (discontinuous) phase.

NOTE This test can be used as a guideline to establish a development method during the development cycle of cosmetic products. In this case, the test can be modified or extended, or both, for example, to make allowance for prior data and different variables (microbial strains, media, incubation conditions exposure time, etc.). Compliance criteria can be adapted to specific objectives. During the development stage of cosmetic products, other methods, where relevant, can be used to determine the preservation efficacy of formulations.

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.

ISO 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*

ISO 18415, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

ISO 21148:2017, *Cosmetics — Microbiology — General instructions for microbiological examination*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 29621, *Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products*