



SLOVENSKI STANDARD SIST EN ISO 11930:2019

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Kozmetika - Mikrobiologija - Vrednotenje protimikrobne zaščite kozmetičnih izdelkov (ISO 11930:2019)

Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product (ISO 11930:2019)

Kosmetische Mittel - Mikrobiologie - Bewertung des antimikrobiellen Schutzes eines kosmetischen Produktes (ISO 11930:2019)

Cosmétiques - Microbiologie - Évaluation de la protection antimicrobienne d'un produit cosmétique (ISO 11930:2019)

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Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product (ISO 11930:2019)

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Kosmetische Mittel - Mikrobiologie - Bewertung des antimikrobiellen Schutzes eines kosmetischen Produktes (ISO 11930:2019)

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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of an identical text or by endorsement, at the latest by August 2019, and conflicting national standards shall be withdrawn at the latest by August 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11930:2012.

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INTERNATIONAL
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Second edition
2019-01

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

*Cosmétiques — Microbiologie — Évaluation de la protection
antimicrobienne d'un produit cosmétique*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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.”

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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