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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11930:2019 sisaldab Euroopa standardi EN ISO 11930:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11930:2019 consists of the English text of the European standard EN ISO 11930:2019.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.02.2019.	Date of Availability of the European standard is 13.02.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

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

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

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

This European Standard was approved by CEN on 27 December 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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of an identical text or by endorsement, at the latest by August 2019, and conflicting national standards shall be withdrawn at the latest by August 2019.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

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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

Contents

Page

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).

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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.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21148 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp