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English Version

**Microbiology - Cosmetics - Guidelines for the application of
ISO standards on Cosmetic Microbiology (ISO/TR
19838:2016)**

Microbiologie - Cosmétique - Lignes directrices pour
l'application des Normes ISO à la microbiologie
cosmétique (ISO/TR 19838:2016)

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European foreword

This document (CEN ISO/TS 19838:2016) 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.

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 217, *Cosmetics*.

Introduction

Every cosmetic manufacturer has a dual responsibility relative to the microbiological quality of its products.

- The first is to ensure that the product, as purchased, is free from the numbers and types of microorganisms that could affect product quality and consumer health. This is generally ensured by applying cosmetic good manufacturing practice (GMP) (see ISO 22716) during the manufacturing and packaging operations and, if necessary, by using **microbial content tests** on finished products.
- The second is to ensure that microorganisms introduced during normal product use will not adversely affect the quality or safety of the product. This is generally ensured by conducting **preservation efficacy tests** (or **challenge tests**) during the development stage of the new product.

In order to ensure product quality and safety for consumers, it is advisable that an appropriate microbiological risk analysis be performed to determine the types of cosmetic products to which this Technical Report would be applicable.

- Products considered to present a low microbiological risk are described in ISO 29621. These products identified as “hostile” and produced in compliance with GMP pose a very low overall risk to the user. Therefore, products that comply with the characteristics outlined in ISO 29621 do not require microbiological testing including both challenge test and end product testing.
- For those products which are not considered “hostile”, the microbiological quality has to be assessed by conducting tests with appropriate methods. ISO TC 217 provides a comprehensive set of standards to assess the antimicrobial preservation of cosmetic products and the microbiological quality of finished products (methods and limits). Manufacturers can decide not to test if they can demonstrate that their products comply with those requirements specified in ISO 17516 and/or ISO 11930.

Microbiology — Cosmetics — Guidelines for the application of ISO standards on Cosmetic Microbiology

1 Scope

This Technical Report gives general guidelines to explain the use of ISO cosmetic microbiological standards depending on the objective (in-market control, product development, etc.) and the product to be tested.

This Technical Report can be used to fulfil the requirements of the ISO standard on microbiological limits (ISO 17516).

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

cosmetic formulation

preparation of raw materials with a qualitatively and quantitatively defined composition

2.2

cosmetic product

finished cosmetic product that has undergone all stages of production, including packaging in its final container for shipment

2.3

sample

one or more representative elements selected from a set to obtain information about that set

2.4.1

microbial content

<quantitative> estimated number of viable aerobic mesophilic microorganisms (bacteria, yeasts and moulds) within a cosmetic

2.4.2

microbial content

<qualitative> detectable specified or non-specified microorganisms within a cosmetic sample

2.5

preservation of a cosmetic formulation

set of means used to avoid microbial proliferation in a cosmetic formulation

EXAMPLE Preservatives, multifunctional compounds, hostile raw materials, extreme pH, low water activity values, etc.

2.6

antimicrobial protection of a cosmetic product

ability of a cosmetic product to overcome microbial contamination that might present a potential risk to the user

Note 1 to entry: The overall antimicrobial protection includes preservation of the formulation, the specific manufacturing process and protective packaging.