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kSIST-TP FprCEN ISO/TR 19838:2016
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Kozmetika - Mikrobiologija - Smernice za uporabo standardov ISO o mikrobiologiji v kozmetiki (ISO/DTR 19838:2015)

Microbiology - Cosmetics - Guidelines for the application of ISO standards on Cosmetic Microbiology (ISO/DTR 19838:2015)

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Microbiologie - Cosmétique - Lignes directrices pour l'application des Normes ISO à la microbiologie cosmétique (ISO/DTR 19838:2015)

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TECHNICAL REPORT

**ISO/TR
19838**

First edition

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

*Microbiologie — Cosmétique — Lignes directrices pour l'application
des Normes ISO à la microbiologie cosmétique*

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ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 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*.

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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 this Technical Report 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.

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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.

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2.7
microbiologically low-risk products
 products whose environment denies microorganisms the physical and chemical requirements for growth and/or survival (hostile products)

Note 1 to entry: This category of low-risk products applies to microbiological contamination which may occur during manufacturing and/or use by the consumer.

Note 2 to entry: A product whose packaging prevents the ingress of microorganisms is considered a microbiological low-risk product during its use.

Note 3 to entry: The inclusion of preservatives or other antimicrobial compounds in a formulation by itself would not necessarily constitute a low-risk product.

2.8
microbiological Risk Assessment (low risk products)
 evaluation of product characteristics to determine if that product may be subject to microbial contamination

Note 1 to entry: These characteristics include the composition of the product, the production conditions, packaging and a combination of these factors (see ISO 29621).

3 Microbial content

3.1 General requirements

There are eight International Standards dealing with the microbial content of cosmetic samples (see [Annex A](#)).

- ISO 16212
- ISO 17516
- ISO 18415
- ISO 18416
- ISO 21149
- ISO 21150
- ISO 22717
- ISO 22718

Additionally, ISO 21148 gives general instructions for carrying out microbiological examinations of cosmetic products.

Because of the large variety of cosmetic products within this field of application, the methods described in these International Standards may not be appropriate for some products in every detail (e.g. certain water immiscible products).

Other methods (e.g. automated) may be substituted for the tests presented here provided that their equivalence has been demonstrated or the method has been otherwise verified.

The possible inhibition of microbial growth by the sample should be neutralized to allow the detection of viable microorganisms. In all cases and whatever the methodology, the neutralization of the antimicrobial properties of the product should be checked and demonstrated.

The study of the neutralization of the antimicrobial activity should be performed when the tests have to be carried out on new products and whenever there is a change in the experimental conditions of the test.

The given International Standards will allow the following:

- the enumeration and detection of mesophilic microorganisms which may grow under aerobic conditions;
- the determination of the absence of specified microorganisms that are of interest for cosmetic products;

and, therefore, to estimate if the product under test complies with the requirements of the International Standard on microbiological limits (ISO 17516).

The test methods are described in the individual standards. The choice of a specific method, or combination of methods, will depend on the purpose for performing the test. It is up to the user to decide which approach is best for each application.

Depending on the expected level of contamination of the sample to be tested, two different approaches can be used (see [Annex A](#)).

- Quantitative tests (enumeration) are to be used when there is no information on the microbiological quality of the sample or if it is expected to be contaminated.
- Qualitative tests (detection) can be used if the sample is presumably free from microbial contamination (e.g. based on product history) and can be very useful from an economical and production time standpoint.

In the event where microorganisms are detected, the presence of specified microorganisms should be checked according to [3.3](#) or [3.4](#).

3.2 Enumeration of mesophilic microorganisms (bacteria, yeasts and moulds)

For bacteria, the enumeration method described in ISO 21149 involves enumeration of colonies on a non-selective agar medium. Enumeration of colonies can be performed by a plate count method or a filtration method using a specified culture medium incubated under defined conditions.

The results are expressed as follows:

“[number] of aerobic mesophilic bacteria per gram or per milliliter of product, expressed as cfu/g or cfu/ml”.

For yeasts and moulds, the method described in ISO 16212 involves enumeration of colonies by a plate count method or a filtration method using a specified culture medium with antibiotic incubated under defined conditions.

An alternative condition using the culture medium without antibiotic is proposed in ISO 16212.

The results are expressed as follows:

“[number] of yeast and mould per gram or per milliliter of product expressed, as cfu/g or cfu/ml”.

3.3 Detection of specified microorganisms

The detection of skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant. The detection of other kinds of microorganisms might be of interest since these microorganisms (including indicators of fecal contamination e.g. *Escherichia coli*) suggest hygienic failure during the manufacturing process.

The methods are described in ISO 18416 (*C. albicans*), ISO 21150 (*E. coli*) ISO 22717 (*P. aeruginosa*), and ISO 22718 (*S. aureus*).