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Cosmetics — Microbiology — Microbiological limits

Cosmétiques — Microbiologie — Limites microbiologiques

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Foreword

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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 392, *Cosmetics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17516:2014), of which it constitutes a minor revision.

The changes are as follows:

— Clause 2 has been added and subsequent clauses have been renumbered;

— the bibliography has been updated.

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.

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Introduction

Every cosmetic manufacturer has a responsibility relative to the microbiological safety and quality of its products to ensure that they have been produced under hygienic conditions. Cosmetic products are not expected to be sterile. However, they shall not contain excessive amounts of microorganisms nor specified microorganisms that have the potential to affect the product quality or consumer safety. Moreover, some cosmetic products which are considered to have low microbiological risk (see ISO 29621 [1]) may not need to be subjected to routine microbiological testing, and manufacturers can decide not to test if they can ensure products meet this standard.

The manufacturer should follow the Good Manufacturing Practices described in ISO 22716 [2] and take the necessary precautions to limit the introduction of microorganisms from raw materials, processing and packaging. When necessary, microbiological testing may be performed using ISO 21148 [3], ISO 21149 [4], ISO 16212 [5], ISO 18415 [6], ISO 18416 [7], ISO 21150 [8], ISO 22717 [9] and ISO 22718 [10].

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Cosmetics — Microbiology — Microbiological limits

1 Scope

This document specifies the acceptable quantitative and qualitative microbiological limits in finished cosmetic products. It is applicable to all cosmetics, and assists interested parties in the assessment of the microbiological quality of cosmetic products.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

— IEC Electropedia: available at https://www.electropedia.org/

3.1
product
portion of an identified cosmetic product received in the laboratory for testing

3.2
aerobic mesophilic microorganisms
mesophilic bacteria, yeast and mould growing aerobically under the conditions specified in ISO 21149 [4] and ISO 16212 [5]

3.3
specified microorganism
aerobic mesophilic bacteria or yeast that is undesirable in a cosmetic product because it can cause skin or eye infection or is an indication of hygienic failure

[SOURCE: ISO 18415:2017 [11], 3.6 — modified «terminology has changed».]

3.4
Escherichia coli
gram-negative rod, motile, smooth colonies

[SOURCE: ISO 21150:2015 [12], 3.6]

3.5
Pseudomonas paraeruginosa
Pseudomonas aeruginosa
gram-negative rod, motile; smooth colonies pigmented brown or greenish

[SOURCE: ISO 22717:2015 [13], 3.6]

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