INTERNATIONAL STANDARD

ISO 17516

First edition
2014-10-01

Cosmetics — Microbiology — Microbiological limits

Cosmétiques — Microbiologie — Limites microbiologiques

Reference number
ISO 17516:2014(E)

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Published in Switzerland

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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. 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 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) 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 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, ISO 21149, ISO 16212, ISO 18415, ISO 18416, ISO 21150, ISO 22717, and ISO 22718.

The objective of this International Standard is to develop acceptable quantitative and qualitative limits for cosmetic finished products.

Cosmetics — Microbiology — Microbiological limits

1 Scope

This International Standard is applicable for all cosmetics and assists interested parties in the assessment of the microbiological quality of the products. Microbiological testing does not need to be performed on those products considered to be microbiologically low risk (see ISO 29621).

2 Terms and definitions

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

2.1
product
portion of an identified cosmetic product received in the laboratory for testing

2.2
aerobic mesophilic microorganisms
mesophilic bacteria, yeast and mould growing aerobically under the conditions specified in ISO 21149 and ISO 16212

2.3
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 18415:2007, definition 3.6 — modified «terminology has changed».]

2.3.1
Escherichia coli
gram-negative rod, motile, smooth colonies

[SOURCE: ISO 21150:2006, definition 3.6]

2.3.2
Pseudomonas aeruginosa
gram-negative rod, motile; smooth colonies pigmented brown or greenish

[SOURCE: ISO 22717:2006, definition 3.6]

2.3.3
Staphylococcus aureus
gram-positive cocci, mainly joined in grape-like clusters, smooth colonies generally pigmented in yellow

[SOURCE: ISO 22718:2006, definition 3.6]

2.3.4
Candida albicans
yeast that forms white to beige, creamy and convex colonies on the surface of a selective medium

[SOURCE: ISO 18416:2007, definition 3.6]

3 Principle

Cosmetics, the raw materials of which they are composed and the conditions under which they are manufactured are not required to be sterile. However the microorganisms present in a product should not

have an adverse effect on consumer safety or product quality during intended or foreseeable use. Therefore, quantitative and/or qualitative microbiological limits are established for finished cosmetic products.

Less than or equal to 1×10^3 CFU per gram or ml of product is considered as an acceptable number for topical applications. However, it is considered that particular attention should be paid to cosmetics specifically intended for use in the eye area, for children under three years of age and on mucous membranes where less than or equal to 1×10^2 CFU per gram or ml of product is considered acceptable. In addition, interpretation of out of limit results shall consider the inherent variability of the plate count method (see Table 1).

Additionally it is expected that product shall be free from *E. coli*, *S. aureus*, *P. aeruginosa* and *C. albicans* in 1 g or 1 ml of product.

This International Standard sets microbiological limits for cosmetics. When necessary, International standard test methods (see Annex A) should be used to assess compliance.

4 Microbiological limits for cosmetics

To ensure the quality of the product and consumer safety it is crucial that the number of non-specified microorganisms recovered from the product remains stable or declines over the product life. The presence of non-specified microorganisms shall not be considered as objectionable, provided that they do not have the ability to grow in the product. This can be based on a risk assessment that includes preservation efficacy studies (e.g. ISO 11930) or by the demonstration that the product cannot support microbial growth (ISO 29621).

Based on these considerations the following microbiological limits mentioned in Table 1 shall apply.

Table 1 — Microbiological limits for cosmetics

Types of microorganisms	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	≤ 1×10^2 CFU per g or ml[a]	≤ 1×10^3 CFU per g or ml[b]
Escherichia coli	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Pseudomonas aeruginosa	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Staphyloccocus aureus	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml

Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if

[a] > 200 CFU/g or ml,

[b] > 2 000 CFU/g or ml.

NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.

Annex A
(normative)

Flowchart for interpretation of test results

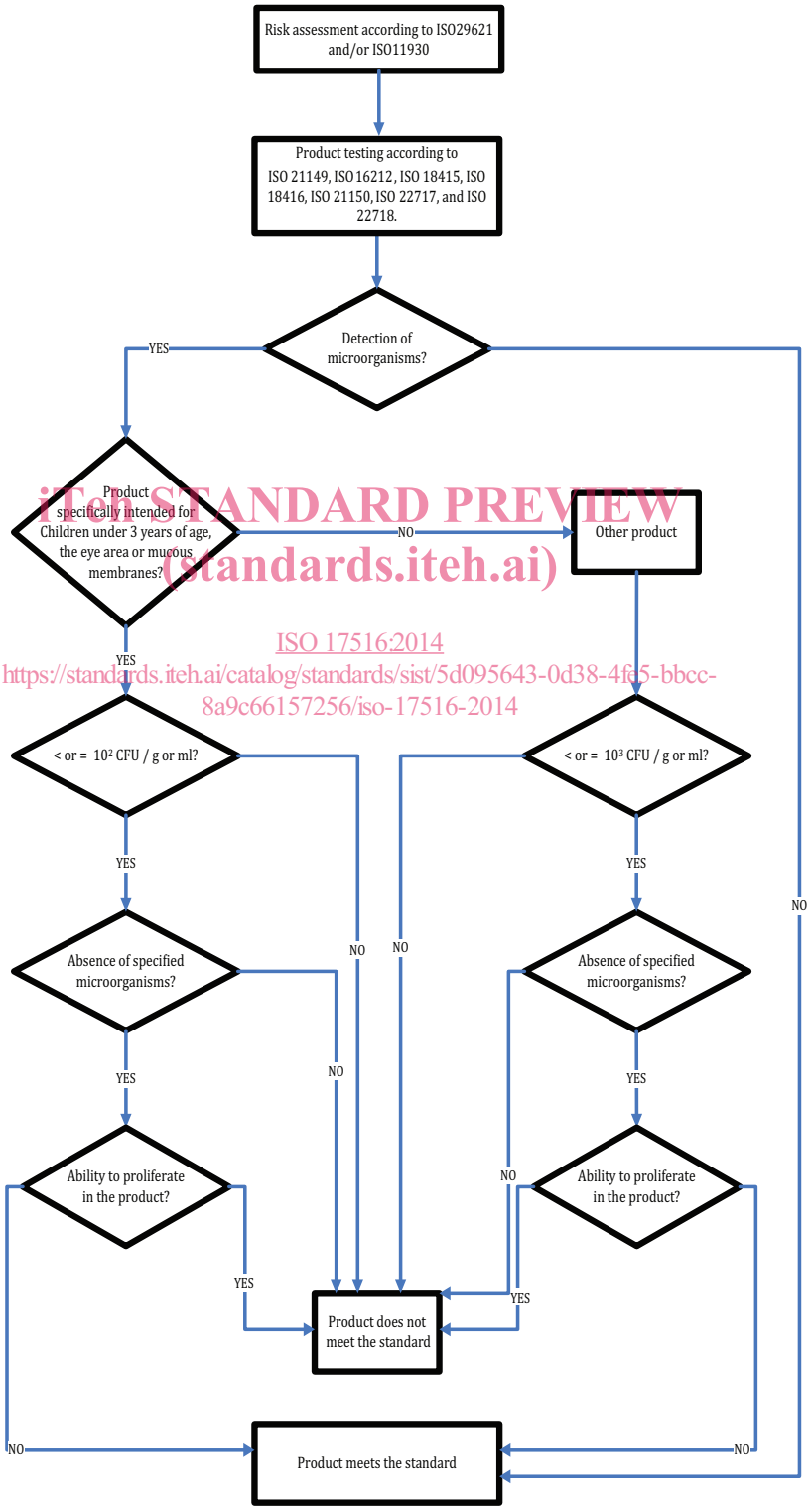

Figure 1 — Flowchart for interpretation of test results