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Cosmetics — Microbiology — Microbiological limits

Cosmétiques — Microbiologie — Limites microbiologiques

ICS 07.100.99; 71.100.99

ISO/CEN PARALLEL PROCESSING

This 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.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 17516 was prepared by Technical Committee 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 specific 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 be subjected to routine microbiological testing and manufactures can decide not to test if they can assure products meet this standard.

The manufacturer should follow the Good Manufacturing Practices (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 may not be performed on those products considered to be microbiologically low risk (see ISO 29621).

2 Terms and Definitions

For the purposes of this International Standard, 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 mold 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. See ISO 18415.

2.3.1

Escherichia coli

Gram-negative rod, motile; smooth colonies. See ISO 21150

2.3.2

Pseudomonas aeruginosa

Gram-negative rod, motile; smooth colonies pigmented brown or greenish. See ISO 22717

2.3.3

Staphylococcus aureus

Gram-positive cocci, mainly joined in grape-like clusters, smooth colonies generally pigmented in yellow

See ISO 22718

2.3.4

Candida albicans

Yeast that forms white to beige, creamy and convex colonies on the surface of a selective medium
See ISO 18416

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 $1x10^3$ CFU per gram or ml 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 and for under three year old children where less than or equal to $1x10^2$ CFU per gram or ml is considered acceptable.

Additionally it is expected that product shall be free from *E. coli*, *S. aureus*, *P. aeruginosa* and *C. albicans* in 1 gram or 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 justified through 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 limits in table 1 shall apply.

Table 1: Microbiological limits for cosmetics

Types of microorganisms	Products specifically intended for under three year old children and eye area	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria, *ISO 21149* plus yeast and mold *ISO 16212*)	$\leq 1x10^2$ CFU per g or ml [1)]	$\leq 1x10^3$ CFU per g or ml [2)]
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
Staphyloccoccus 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 (See USP 35-<61> interpretation of the results):

1): result considered out of limit if > 200 CFU/g or ml

2): result considered out of limit if > 2000 CFU/g or ml