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Cosmetics — Microbiology — Microbiological limits

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Table of changes

Change No.	Date	Scope

National foreword

This South African standard was prepared by National Committee SABS/TC 217, *Cosmetics*, in accordance with procedures of the South African Bureau of Standards, in compliance with annex 3 of the WTO/TBT agreement.

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INTERNATIONAL STANDARD

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First edition
2014-10-01

Cosmetics — Microbiology — Microbiological limits

Cosmétiques — Microbiologie — Limites microbiologiques

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Foreword

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

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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) 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.

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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

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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.		

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Annex A
(normative)

Flowchart for interpretation of test results

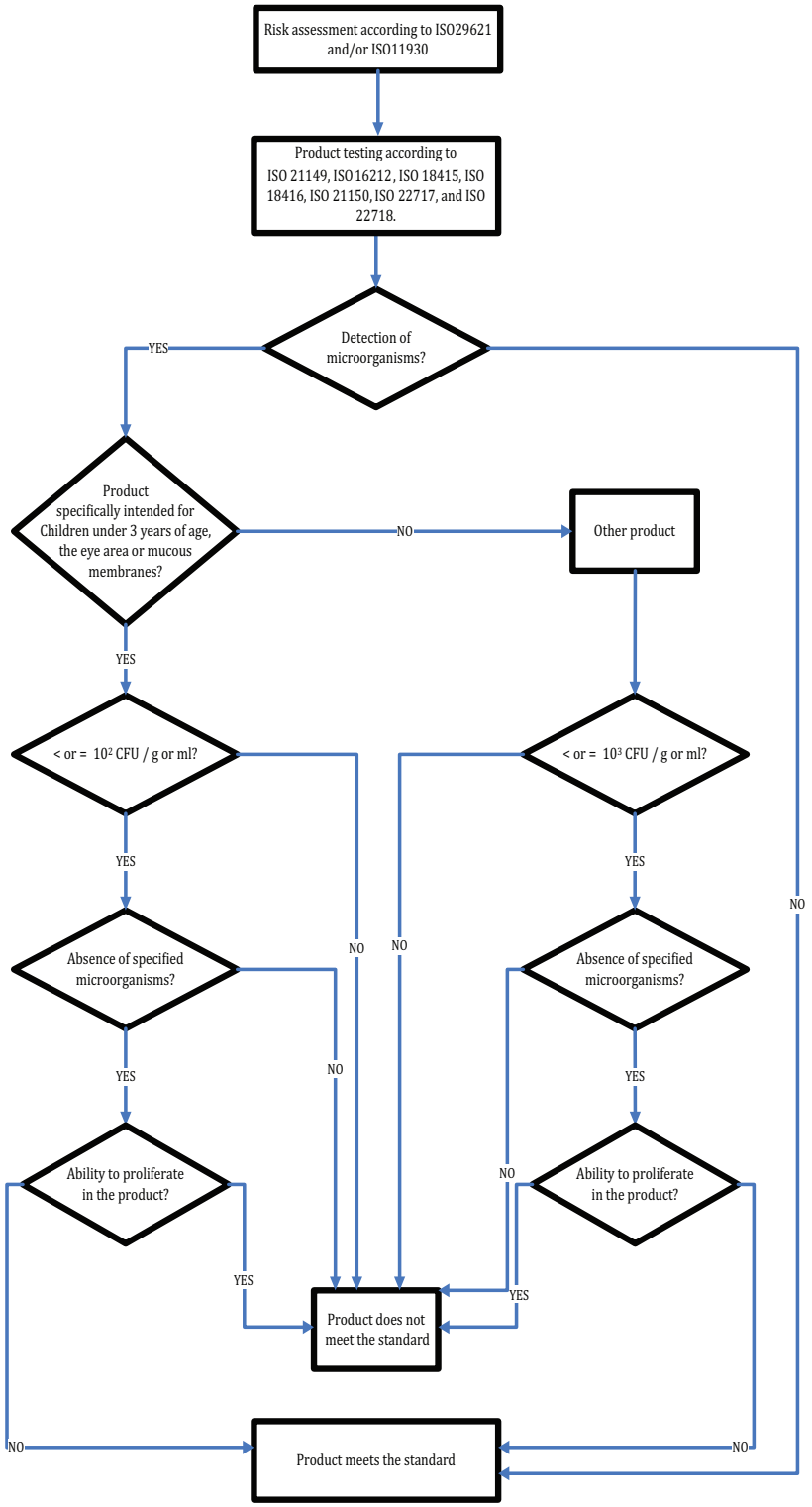


Figure 1 — Flowchart for interpretation of test results

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Bibliography

[1] ISO 11930, *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*

[2] ISO 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*

[3] ISO 18415:2007, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

[4] ISO 18416:2007, *Cosmetics — Microbiology — Detection of Candida albicans*

[5] ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*

[6] ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

[7] ISO 21150:2006, *Cosmetics — Microbiology — Detection of Escherichia coli*

[8] ISO 22716, *Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices*

[9] ISO 22717:2007, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

[10] ISO 22718:2006, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

[11] ISO 29621, *Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products*

[12] European Union: The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation 8th revision, 2012-12-11, § 4.4. ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

[13] Saudi Arabia: Compliance Verification Guidelines CVG.403 dated 17 September 09 Page 6

[14] Tanzania: Cosmetic Regulations of July 2006 Art. 13c & Annex 7

[15] ASEAN Cosmetic Directive / 8th ACC Meeting – June 2007

[16] China: Hygienic Standard of Cosmetics 2007 (§ 4.3.1)

[17] Indian standards: IS 6356 toothpaste, 2010

[18] Indian standards: IS 9875 Lipsticks, 2010

[19] Iranian standard: ISIRI 3271 Microbiology of shampoo -Specifications and test methods, 2010

[20] Iranian standard: ISIRI 3978 Microbiology of cream and lotion-Specifications and test methods, 2010

[21] Iranian standard: ISIRI 6342 Microbiology of toothpaste-Specifications and test methods, 2010

[22] Japan – JCIA, The ministry of health Yakkan No, 229 (7 September 1972)

[23] U.S. Pharmacopeia - USP 35- <61> Microbial examination of nonsterile products: microbial enumeration tests <1111> Microbial examination of nonsterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use

[24] Andean Community: "Resolution 1418 – Adiciones a la resolucion 797 Límites de conteni-do microbiologico de productos cosmeticos": Gaceta oficial del acuerdo de Cartagena Año XXVIII – Numèro 1953 13 June 2011

[25] Mercosul/GM/RES. Nº 51/98- parâmetros de controle microbiologico para produtos de hygiene pessoal, cosmeticos e perfumes

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[26] MCCA (Guatemala, El Salvador, Nicaragua, Honduras et Costa Rica): Reglamento técnico Centroamericano RTCA 71.03.45:07 Productos cosmeticos. Verificacion de la calidad

[27] MICROBIOLOGY GUIDELINES CTFA 2007

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