BS EN ISO 17516:2014

BSI Standards Publication

Cosmetics — Microbiology — Microbiological limits

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO 17516:2014.

The UK participation in its preparation was entrusted to Technical Committee CW/217, Cosmetics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 78701 0

ICS 07.100.99; 71.100.99

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2014.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17516

October 2014

ICS 07.100.99; 71.100.99

English Version

Cosmetics - Microbiology - Microbiological limits (ISO 17516:2014)

Cosmétiques - Microbiologie - Limites microbiologiques (ISO 17516:2014)

Kosmetische Mittel - Mikrobiologie - Mikrobiologische Grenzwerte (ISO 17516:2014)

This European Standard was approved by CEN on 9 August 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 17516:2014 E

Foreword

This document (EN ISO 17516:2014) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17516:2014 has been approved by CEN as EN ISO 17516:2014 without any modification.

Contents

Page

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

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. 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*.

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.

INTERNATIONAL STANDARD **ISO 17516:2014(E)**

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

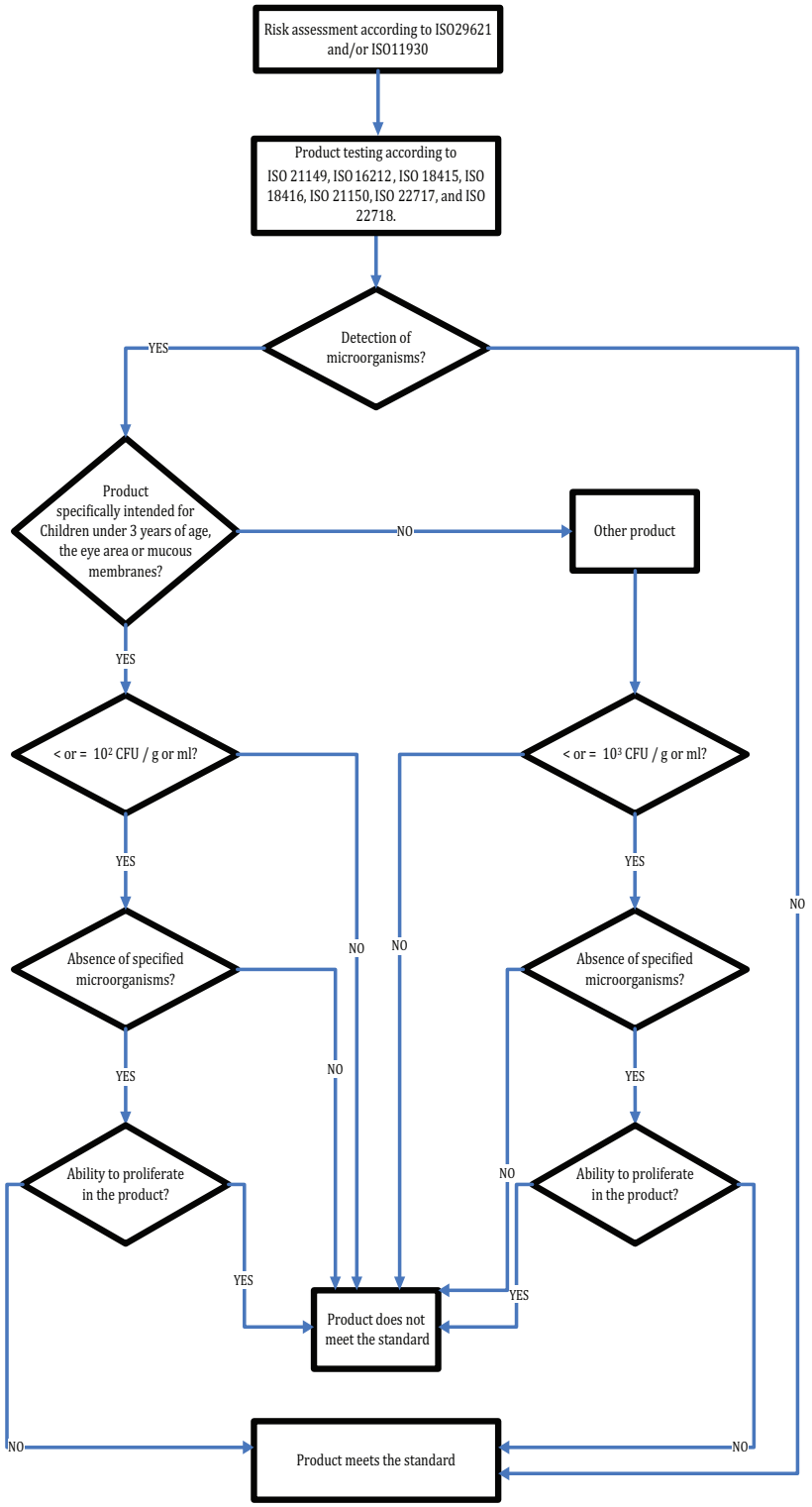

Figure 1 — Flowchart for interpretation of test results

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

[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

This page deliberately left blank

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™