BS EN ISO 17516:2014

BSI Standards Publication

Cosmetics — Microbiology — Microbiological limits

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.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.

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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

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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.

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