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NSAI Standards

Irish Standard
I.S. EN ISO 17516:2014

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17516

October 2014

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English Version

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

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

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

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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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INTERNATIONAL STANDARD

ISO 17516

First edition
2014-10-01

Cosmetics — Microbiology — Microbiological limits

Cosmétiques — Microbiologie — Limites microbiologiques

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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.

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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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