

**SLOVENSKI STANDARD**  
**oSIST prEN ISO 17516:2013**  
**01-september-2013**

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**Kozmetika - Mikrobiološke mejne vrednosti (ISO/DIS 17516:2013)**

Cosmetics - Microbiological limits (ISO/DIS 17516:2013)

Kosmetische Mittel - Mikrobiologische Grenzwerte (ISO/DIS 17516:2013)

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**ICS:**

07.100.99	Drugi standardi v zvezi z mikrobiologijo	Other standards related to microbiology
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

**oSIST prEN ISO 17516:2013**

**en,fr,de**





## DRAFT INTERNATIONAL STANDARD ISO/DIS 17516

ISO/TC 217

Secretariat: ISIRI

Voting begins on  
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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

## Cosmetics — Microbiology — Microbiological limits

*Cosmétiques — Microbiologie — Limites microbiologiques*

ICS 07.100.99; 71.100.99

## iTeh STANDARD PREVIEW

## 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.

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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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## 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*.

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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 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.

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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 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*

**ISO/DIS 17516**

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

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**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  $1 \times 10^3$  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  $1 \times 10^2$  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.