



SLOVENSKI STANDARD
SIST EN ISO 21149:2009

01-oktober-2009

Kozmetika - Mikrobiologija - Ugotavljanje prisotnosti in števila aerobnih mezofilnih bakterij (ISO 21149:2006)

Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2006)

Kosmetik - Mikrobiologie - Zählung und Nachweis von aeroben mesophilen Bakterien (ISO 21149:2006)

Cosmétiques - Microbiologie - Dénombrement et détection des bactéries aérobies mésophiles (ISO 21149:2006)

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 21149

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English Version

**Cosmetics - Microbiology - Enumeration and detection of
aerobic mesophilic bacteria (ISO 21149:2006)**

Cosmétiques - Microbiologie - Dénombrement et détection
des bactéries aérobies mésophiles (ISO 21149:2006)

Kosmetik - Mikrobiologie - Zählung und Nachweis von
aeroben mesophilen Bakterien (ISO 21149:2006)

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 21149:2006 has been prepared by Technical Committee ISO/TC 217 “Cosmetics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21149:2009 by Technical Committee CEN/SS H99 “Products for household and leisure use - Undetermined” the secretariat of which is held by CMC.

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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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INTERNATIONAL STANDARD

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Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria

*Cosmétiques — Microbiologie — Dénombrement et détection des
bactéries aérobies mésophiles*

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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 21149 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

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Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria

1 Scope

This International Standard gives general guidelines for enumeration and detection of mesophilic aerobic bacteria present in cosmetics,

- by counting the colonies on agar medium after aerobic incubation, or
- by checking the absence of bacterial growth after enrichment.

Because of the large variety of cosmetic products within this field of application, this method may not be appropriate for some products in every detail (e.g. certain water immiscible products). Other methods (e.g. automated) may be substituted for the tests presented here provided that their equivalence has been demonstrated or the method has been otherwise validated.

If needed, microorganisms enumerated or detected may be identified using suitable identification tests described in the standards given in the Bibliography.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis, so as to determine the types of cosmetic products to which this International Standard is applicable. Products considered to present a low microbiological risk include those with low water activity, hydro-alcoholic products, extreme pH values, etc.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21148:2005, *Cosmetics — Microbiology — General instructions for microbiological examination*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

aerobic mesophilic bacteria

mesophilic bacteria growing aerobically under the conditions specified in this International Standard

NOTE In the described conditions, other types of microorganisms (e.g. yeast, mould) can be detected.

3.2

product

portion of an identified cosmetic product received in the laboratory for testing

ISO 21149:2006(E)**3.3****sample**

portion of the product (at least 1 g or 1 ml) which is used in the test to prepare the initial suspension

3.4**initial suspension**

suspension (or solution) of a sample in a defined volume of an appropriate liquid (diluent, neutralizer, broth or combination of them)

3.5**sample dilution**

dilution of the initial suspension

4 Principle**4.1 General**

This method involves enumeration of colonies on a non-selective agar medium or by the presence or absence of bacterial growth after enrichment. The possible inhibition of microbial growth by the sample shall be neutralized to allow the detection of viable microorganism [1]. In all cases and whatever the methodology, the neutralization of the antimicrobial properties of the product shall be checked and validated [2] [3] [4].

4.2 Plate count

Plate count consists of the following steps.

- Preparation of poured plates or spread plates, using a specified culture medium, and inoculation of the plates using a defined quantity of the initial suspension or dilution of the product.
- Aerobic incubation of the plates at $32,5\text{ °C} \pm 2,5\text{ °C}$ for $72\text{ h} \pm 6\text{ h}$.
- Counting the number of colony forming units (CFU) and calculation of the number of aerobic mesophilic bacteria per millilitre or per gram of product.

4.3 Membrane filtration

Membrane filtration consists of the following steps.

- Transfer a suitable amount of the sample prepared as validated in the filtration apparatus wetted with a small volume of an appropriate sterile diluent, filter immediately and wash according to the validated procedure (see 13.3.4). Transfer the membrane filter onto the surface of the specified agar medium as specified in ISO 21148.
- Aerobic incubation of the membranes at $32,5\text{ °C} \pm 2,5\text{ °C}$ for $72\text{ h} \pm 6\text{ h}$.
- Counting the number of colony forming units (CFU) and calculation of the number of aerobic mesophilic bacteria per millilitre or per gram of product.