# SLOVENSKI STANDARD
# kSIST FprEN ISO 22717:2015

**01-september-2015**

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**Kozmetika - Mikrobiologija - Ugotavljanje prisotnosti bakterije Pseudomonas aeruginosa (ISO/FDIS 22717:2015)**

Cosmetics - Microbiology - Detection of Pseudomonas aeruginosa (ISO/FDIS 22717:2015)

Kosmetische Mittel - Mikrobiologie - Nachweis von Pseudomonas aeruginosa (ISO/FDIS 22717:2015)

Cosmétiques - Microbiologie - Détection de Pseudomonas aeruginosa (ISO/FDIS 22717:2015)



**Ta slovenski standard je istoveten z:** **FprEN ISO 22717**

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| 07.100.99 | Drugi standardi v zvezi z mikrobiologijo | Other standards related to microbiology |
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# Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa

*Cosmétiques — Microbiologie — Recherche de Pseudomonas aeruginosa*



**Please see the administrative notes on page iii**



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## ISO/CEN PARALLEL PROCESSING

This final 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. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

**Positive votes shall not be accompanied by comments.**

**Negative votes shall be accompanied by the relevant technical reasons.**

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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.

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 (see 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 (see 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*.

This second edition cancels and replaces the first edition (ISO 22717:2006), of which it constitutes a minor revision.

# Introduction

Microbiological examinations of cosmetic products shall be carried out according to an appropriate microbiological risk analysis in order to ensure their quality and safety for consumers.

Microbiological risk analysis depends on several parameters such as the following:

— potential alteration of cosmetic products;

— pathogenicity of microorganisms;

— site of application of the cosmetic product (hair, skin, eyes, mucous membranes, etc.);

— type of users (adults, children under 3 years).

For cosmetics and other topical products, the detection of skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant. The detection of other kinds of microorganism might be of interest since these microorganisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during the manufacturing process.



 

# Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa

## 1 Scope

This International Standard gives general guidelines for the detection and identification of the specified microorganism *Pseudomonas aeruginosa* in cosmetic products. Microorganisms considered as specified in this International Standard might differ from country to country according to national practices or regulations.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis to determine the types of cosmetic product to which this International Standard is applicable. Products considered to present a low microbiological (see ISO 29621) risk include those with low water activity, hydro-alcoholic products, extreme pH values, etc.

The method described in this International Standard is based on the detection of *Pseudomonas aeruginosa* in a non-selective liquid medium (enrichment broth), followed by isolation on a selective agar medium. Other methods may be appropriate, depending on the level of detection required.

NOTE For the detection of *Pseudomonas aeruginosa*, subcultures can be performed on non-selective culture media followed by suitable identification steps (e.g. using identification kits).

Because of the large variety of cosmetic products within this field of application, this method may not be appropriate in every detail for some products (e.g. certain water immiscible products). Other International Standards (ISO 18415) may be appropriate. 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.



## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

EN 12353, *Chemical disinfectants and antiseptics — Preservation of microbial strains used for the determination of bactericidal and fungicidal activity*

## 3 Terms and definitions

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

**3.1**
**product**
portion of an identified cosmetic product received in the laboratory for testing

**3.2**
**sample**
portion of the product (at least 1 g or 1 ml) that is used in the test to prepare the initial suspension

**3.3**
**initial suspension**
suspension (or solution) of the sample in a defined volume of an appropriate enrichment broth

**3.4**
**sample dilution(s)**
dilution(s) of the initial suspension

**3.5**
**specified micro-organism**
aerobic mesophilic bacteria or yeast that is undesirable in a cosmetic product and is recognized as a skin pathogen species that may be harmful for human health or as indication of hygienic failure in the manufacturing process

**3.6**
***Pseudomonas aeruginosa***
Gram-negative rod, motile; smooth colonies pigmented brown or greenish

Note 1 to entry: The main characteristics for identification are: growth on selective cetrimide agar medium, oxidase positive, production of diffusible fluorescent pigments and production of a soluble phenazine pigment (pyocyanin) in suitable media.

Note 2 to entry: *Pseudomonas aeruginosa* may be isolated from a wide variety of environmental sources, especially in water and has a very high potential to spoil many different substrates. It may produce infections of human skin or eye area. It is undesirable in cosmetic products for its potential pathogenicity and its capacity to affect the physico-chemical properties of the cosmetic formula.

**3.7**
**enrichment broth**
non-selective liquid medium containing suitable neutralizers and/or dispersing agents and demonstrated to be suitable for the product under test



## 4 Principle

The first step of the procedure is to perform an enrichment by using a non-selective broth medium to increase the number of microorganisms without the risk of inhibition by the selective ingredients that are present in selective/differential growth media.



The second step of the test (isolation) is performed on a selective medium followed by identification tests.

The possible inhibition of microbial growth by the sample shall be neutralized to allow the detection of viable microorganisms.[1] In all cases and whatever the methodology, the neutralization of the antimicrobial properties of the product shall be checked and demonstrated (see Clause 11).

## 5 Diluents and culture media

### 5.1 General

General instructions are given in ISO 21148. When water is mentioned in this International Standard, use distilled water or purified water as specified in ISO 21148.

The enrichment broth is used to disperse the sample and to increase the initial microbial population. It may contain neutralizers if the specimen to be tested has antimicrobial properties. The efficacy of the neutralization shall be demonstrated (see Clause 11). Information relative to suitable neutralizers is given in Annex B.

The enrichment broth (5.3.3.1), or any of the ones listed in Annex A, is suitable for checking the presence of *Pseudomonas aeruginosa* in accordance with this International Standard provided that it has been demonstrated to be suitable in accordance with Clause 11.

Other diluents and culture media may be used if they can be demonstrated to be suitable for use.

 

## 5.2 Diluent for the bacterial suspension (tryptone sodium chloride solution)

### 5.2.1 General

The diluent is used for the preparation of bacterial suspension used for the suitability test procedure (see Clause 11).

### 5.2.2 Composition

| | |
|---|---|
| — tryptone, pancreatic digest of casein | 1,0 g |
| — sodium chloride | 8,5 g |
| — water | 1 000 ml |

### 5.2.3 Preparation

Dissolve the components in water by mixing while heating. Dispense into suitable containers. Sterilize in the autoclave at 121 °C for 15 min.

After sterilization and cooling down, the pH shall be equivalent to 7,0 ± 0,2 when measured at room temperature.

## 5.3 Culture media



### 5.3.1 General

Culture media may be prepared using the descriptions provided below or from dehydrated culture media according to the instructions of the manufacturer. The instructions provided by the supplier of the media should be followed.



NOTE Ready-to-use media can be used when their composition and/or growth yields are comparable to those of the formulae given herein.

### 5.3.2 Agar medium for the suitability test (soybean–casein digest agar medium or tryptic soy agar)

#### 5.3.2.1 Composition

| | |
|---|---|
| — pancreatic digest of casein | 15,0 g |
| — papaic digest of soybean meal | 5,0 g |
| — sodium chloride | 5,0 g |
| — agar | 15,0 g |
| — water | 1 000 ml |

#### 5.3.2.2 Preparation

Dissolve the components or the dehydrated complete medium in the water by mixing while heating. Dispense the medium into suitable containers. Sterilize in the autoclave at 121 °C for 15 min.

After sterilization and cooling down, the pH shall be equivalent to 7,3 ± 0,2 when measured at room temperature.