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Kosmetika – Mikrobiologi – Detektion av Staphylococcus aureus (ISO 22718:2015)

Cosmetics – Microbiology – Detection of Staphylococcus aureus (ISO 22718:2015)



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Denna standard ersätter SS-EN ISO 22718:2009, utgåva 1.

The European Standard EN ISO 22718:2015 has the status of a Swedish Standard. This document contains the official English version of EN ISO 22718:2015.

This standard supersedes the Swedish Standard SS-EN ISO 22718:2009, edition 1.

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EUROPEAN STANDARD

EN ISO 22718

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Cosmetics - Microbiology - Detection of Staphylococcus aureus (ISO 22718:2015)

Cosmétiques - Microbiologie - Détection de Staphylococcus aureus (ISO 22718:2015)

Kosmetische Mittel - Mikrobiologie - Nachweis von Staphylococcus aureus (ISO 22718:2015)

This European Standard was approved by CEN on 26 September 2015.

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European foreword

This document (EN ISO 22718:2015) 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of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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Endorsement notice

The text of ISO 22718:2015 has been approved by CEN as EN ISO 22718:2015 without any modification.

Introduction

Microbiological examinations of cosmetic products are 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);
- 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 because they can cause skin or eye infections. 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 *Staphylococcus aureus*

1 Scope

This International Standard gives general guidelines for the detection and identification of the specified microorganism *Staphylococcus aureus* 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 *Staphylococcus aureus* in a non-selective liquid medium (enrichment broth), followed by isolation on a selective agar medium. Other methods may be appropriate dependent on the level of detection required.

NOTE For the detection of *Staphylococcus aureus*, 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 for some products in every detail (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 shown to be suitable.

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 test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) 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

dilution of the initial suspension

3.5 specified microorganism

aerobic mesophilic bacterium 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 an indication of hygienic failure in the manufacturing process

3.6 *Staphylococcus aureus*

gram-positive cocci, mainly aggregated in grape-like clusters, smooth colonies generally pigmented in yellow

Note 1 to entry: The main characteristics for identification are: growth on specific selective medium, catalase positive, coagulase positive.

Note 2 to entry: *Staphylococcus aureus* is an opportunistic pathogen for humans that can also be present on the skin of healthy people without causing disorder for them. It is undesirable in cosmetic products due to its potential pathogenicity.

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 *Staphylococcus aureus* 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 it has been demonstrated that they are 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 $7,0 \pm 0,2$ 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 from 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 (see [Clause 11](#)) [soybean-casein digest agar medium (SCDA) or tryptic soy agar (TSA)]

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 $7,3 \pm 0,2$ when measured at room temperature.