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Kosmetika – Mikrobiologi – Detektion av Staphylococcus aureus (ISO 22718:2006)

Cosmetics – Microbiology – Detection of Staphylococcus aureus (ISO 22718:2006)

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The European Standard EN ISO 22718:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 22718:2009.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22718

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English Version

Cosmetics - Microbiology - Detection of Staphylococcus aureus (ISO 22718:2006)

Cosmétiques - Microbiologie - Détection de Staphylococcus aureus (ISO 22718:2006)

Kosmetik - Mikrobiologie - Nachweis von Staphylococcus aureus (ISO 22718:2006)

This European Standard was approved by CEN on 30 May 2009.

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Contents

Page

Foreword

The text of ISO 22718:2006 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 22718:2009.

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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.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

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Endorsement notice

The text of ISO 22718:2006 has been approved by CEN as a EN ISO 22718:2009 without any modification.

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:

— potential alteration of cosmetic products;

— pathogenicity of micro-organisms;

— 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 micro-organism might be of interest since these micro-organisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during manufacturing process.

Cosmetics — Microbiology — Detection of *Staphylococcus aureus*

1 Scope

This International Standard gives general guidelines for the detection and identification of the specified micro-organism *Staphylococcus aureus* in cosmetic products. Micro-organisms 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 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 [10]) 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 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*

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
Staphylococcus aureus
Gram-positive cocci, mainly joined in grape-like clusters, smooth colonies generally pigmented in yellow

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

NOTE 2 *Staphylococcus aureus* is an opportunistic pathogen bacterium for humans that can be also 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 validated 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 micro-organisms without the risk of inhibition by the selective ingredients that are present in selective/differential growth media.

The second step (isolation) of the test 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 micro-organisms [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].

5 Diluents and culture media

5.1 General

General instructions are given in ISO 21148. When water is mentioned in this document, 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 following enrichment broth is suitable for checking the presence of *Staphylococcus aureus* in accordance with this International Standard provided that it is validated 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 validation 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 whilst 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 from the manufacturer. The instructions provided by the supplier of the media should be followed.

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

5.3.2 Agar medium for validation (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 ± 0,2 when measured at room temperature.