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Cosmetics — Microbiology — Detection of Candida albicans

Cosmétiques — Microbiologie — Détection de Candida albicans

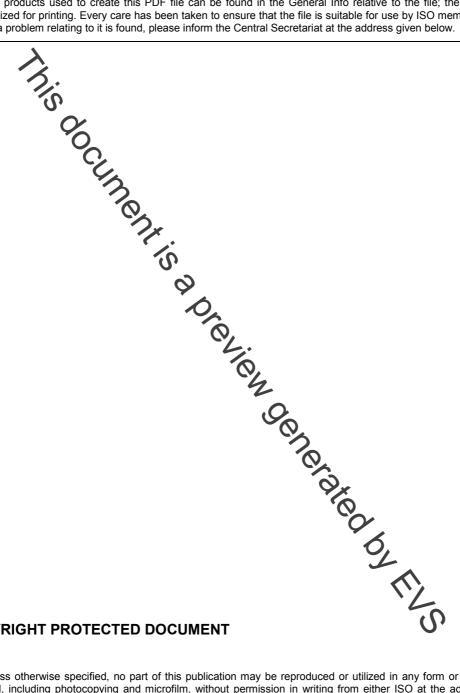


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Contents	Page
Foreword	in

Forewo	ordi
Introdu	iction
1	Scope
2	Normative references
3	Terms and efinitions
4	Principle
5 5.1 5.2 5.3	Diluents and culture media General Diluent for the yeast suspension (tryptone sodium chloride solution) Culture media
6	Apparatus and glassware.
7	Strains of microorganisms
8	Handling of cosmetic products and laboratory samples
9 9.1 9.2 9.3 9.4	Procedure
10	Expression of the results (detection of Candida albicans)
11 11.1 11.2 11.3	Neutralization of the antimicrobial properties of the product
12	Test report
Annex	A (informative) Other media1
Annex	B (informative) Neutralizers of antimicrobial activity of preservatives and rinsing liquids 19
Bibliog	Expression of the results (detection of Candida albicans) Neutralization of the antimicrobial properties of the product

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 traison 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 18416 was prepared by Technical Committee ISO/TC 217, Cosmetics.

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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:

- potential alteration of cosmetic products;
- pathogenicity of microorganisms;
- site of application of the cosmetic product (hair, skin, eyes, mucous membranes);
- type of user (adults, children, including under 3 years).

For cosmetics and other topical products, the detection of *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 those microorganisms (including indicators of faecal contamination, e.g. *Escherichia coli*) suggest hygienic failure during the manufacturing process.

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Cosmetics — Microbiology — Detection of Candida albicans

1 Scope

This International Standard gives general guidelines for the detection and identification of the specified microorganism *Candida albicans* 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 so as 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, those with extreme pH values, etc.

The method described in this International Standard is based on the detection of *Candida albicans* 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 *Candida albicas*, 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 might not be suited in every detail to some products (e.g. certain vater-immiscible products). Other International Standards (e.g. ISO 18415) might be appropriate. Other methods (e.g. automated) can be substituted for the test 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 test organisms used for the determination of bactericidal, mycobactericidal, sporicidal 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