SLOVENSKI STANDARD
kSIST FprEN ISO 18416:2015

01-september-2015

Kozmetika - Mikrobiologija - Ugotavljanje prisotnosti kvasovke Candida albicans (ISO/FDIS 18416:2015)

Cosmetics - Microbiology - Detection of Candida albicans (ISO/FDIS 18416:2015)

Kosmetische Mittel - Mikrobiologie - Nachweis von Candida albicans (ISO/FDIS 18416:2015)

Cosmétiques - Microbiologie - Détection de Candida albicans (ISO/FDIS 18416:2015)

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Ta slovenski standard je istoveten z: **FprEN ISO 18416**

ICS:

07.100.99	Drugi standardi v zvezi z mikrobiologijo	Other standards related to microbiology
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
18416**

ISO/TC **217**

Secretariat: ISIRI

Voting begins on:
2015-06-25

Voting terminates on:
2015-08-25

Cosmetics — Microbiology — Detection of Candida albicans

Cosmétiques — Microbiologie — Détection de Candida albicans

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Please see the administrative notes on page iii

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Reference number
ISO/FDIS 18416:2015(E)

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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

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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).

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The committee responsible for this document is ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 18416:2007), of which it constitutes a minor revision.

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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 the following:

— 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 (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 *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 albicans*, subcultures can be performed on non-selective culture media followed by suitable identification steps (e.g. using identification kits).

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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 water-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.

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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, 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

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

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3.4
sample dilution
dilution of the initial suspension

3.5
specified microorganisms
aerobic mesophilic bacteria or yeast that is undesirable in a cosmetic product because it can cause skin or eye infections or is an indication of hygienic failure

3.6
Candida albicans
yeast that form white to beige, creamy and convex colonies on the surface of a selective medium

Note 1 to entry: The main characteristic for identification is the production of germ tube and/or pseudomycelium and chlamydospore when the test is performed following the method specified in this International Standard.

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

To prevent the possible inhibition of microbial growth by the sample it 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 *Candida albicans* 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 yeast suspension (tryptone sodium chloride solution)

5.2.1 General

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

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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 of the solution, 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 in accordance with the manufacturer's instructions. 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.

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5.3.2 Agar medium for suitability test (see Clause 11)

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5.3.2.1 Sabouraud dextrose agar (SDA)

5.3.2.1.1 Composition

— dextrose 40,0 g

— peptic digest of animal tissue 5,0 g

— pancreatic digest of casein 5,0 g

— agar 15,0 g

— water 1 000 ml

5.3.2.1.2 Preparation

Dissolve the components or the dehydrated complete medium in the water by heating. Dispense the medium into suitable containers. Sterilize in an autoclave at 121 °C for 15 min. After sterilization the pH shall be equivalent to 5,6 ± 0,2 when measured at room temperature.

5.3.2.2 Other agar media for suitability test

Other agar media for suitability test may be used as appropriate (see Annex A).

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