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Cosmetics — Microbiology — Detection of specified and non-specified microorganisms

*Cosmétiques — Microbiologie — Détection des micro-organismes
spécifiés et non spécifiés*



Reference number
ISO 18415:2007(E)

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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Principle.....	3
5 Diluents and culture media.....	3
5.1 General.....	3
5.2 Diluent for the microbial suspension (tryptone sodium chloride solution)	3
5.3 Culture media	4
6 Apparatus and glassware	5
7 Strains of microorganism	5
8 Handling of cosmetic products and laboratory samples	6
9 Procedure	6
9.1 General recommendations	6
9.2 Preparation of the initial suspension in the enrichment broth	6
9.3 Incubation of the initial suspension	7
9.4 Isolation of specified and non-specified microorganisms	7
9.5 Procedure for identification of the specified microorganism: <i>Pseudomonas aeruginosa</i>	7
9.6 Procedure for identification of the specified microorganism: <i>Escherichia coli</i>	8
9.7 Procedure for identification of the specified microorganism: <i>Staphylococcus aureus</i>	8
9.8 Procedure for the identification of the specified microorganism: <i>Candida albicans</i>	9
9.9 Procedure for the identification of non-specified microorganisms	9
10 Expression of the results	10
10.1 Detection of specified microorganisms	10
10.2 Detection of non-specified microorganisms	10
10.3 Absence of microorganisms	10
11 Neutralization of the antimicrobial properties of the product.....	10
11.1 General.....	10
11.2 Preparation of inoculum	10
11.3 Validation of detection method by enrichment	11
12 Test report	12
Annex A (informative) General scheme for identification of microorganisms	13
Annex B (informative) Other Media	14
Annex C (informative) Neutralizers of antimicrobial activity of preservatives and rinsing liquids	17
Bibliography	18

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.

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 18415 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This corrected version of ISO 18415:2007 contains the following corrections:

- p. 2, 3.6.1: modification of definition;
- p. 3, 3.8: correction of term's number;
- p.8, 9.7.1: correction of text in the second paragraph.

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 skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant because they can cause skin or eye infection. The detection of other kinds of microorganisms might be of interest since these microorganisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during manufacturing process.

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Cosmetics — Microbiology — Detection of specified and non-specified microorganisms

1 Scope

This International Standard gives general guidelines for the detection and identification of specified microorganisms in cosmetic products as well as for the detection and identification of other kinds of aerobic mesophilic non-specified microorganisms in cosmetic products.

Microorganisms considered as specified in this International Standard might differ from country to country according to national practices or regulations. Most of them considered as specified microorganisms include one or more of the following species: *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Candida albicans*.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis in order 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 microbial growth in a non-selective liquid medium (enrichment broth) suitable to detect microbial contamination, followed by isolation of microorganisms on non-selective agar media. Other methods can be appropriate depending on the level of detection required.

In this International Standard specific indications are given for identification of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Candida albicans*. Other microorganisms that grow under the conditions described in this International Standard, may be identified by using suitable tests according to a general scheme (see Annex A). Other standards (e.g., ISO 16716, ISO 21150, ISO 22717, ISO 22718) may be appropriate.

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 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*