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Cosmétiques - Microbiologie - Instructions générales pour les examens microbiologiques (ISO 21148:2017)

Kosmetische Mittel - Mikrobiologie - Allgemeine Anleitungen zur mikrobiologischen Untersuchung (ISO 21148:2017)

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European foreword

This document (EN ISO 21148:2017) 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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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INTERNATIONAL STANDARD

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Cosmetics — Microbiology — General instructions for microbiological examination

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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.

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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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21148:2005), of which it constitutes a minor revision.

It also incorporates the Technical Corrigendum ISO 21148:2005/Cor 1:2006.

The following changes have been made:

a) in the Introduction, "validated" was changed to "demonstrated to be suitable";

b) in Clause 6, "validation of the methodology" was changed to "verification of the methods' suitability";

c) in 8.2.1, "validated" was changed to "demonstrated to be suitable";

d) in Clause 13, "validated" was changed to "demonstrated";

e) in A.5, "validated" was changed to "demonstrated to be suitable";

f) in B.3, editorial changes were applied.

Introduction

The purpose of this document is to help ensure that the general techniques used for conducting cosmetic microbiological examinations are the same in other laboratories that adopt these standards, to help achieve homogeneous results in different laboratories and to contribute towards the protection of the health of the laboratory personnel by preventing risk of infection.

When conducting microbiological examinations for cosmetic products, it is especially important that:

— only those microorganisms which are present in the samples be isolated or enumerated;

— the microorganisms do not contaminate the environment.

In order to achieve this, it is necessary to pay attention to personal hygiene and to use working techniques which ensure, as far as possible, exclusion of extraneous contamination.

Since, in this document, it is possible to give only a few examples of the precautions to be taken during microbiological examinations, a thorough knowledge of the microbiological techniques and of the microorganisms involved is essential. It is important that the analyses be conducted as accurately as possible, including calculation of the number of microorganisms.

A large number of manipulations can, for example, unintentionally lead to cross-contamination and the analyst should always verify the accuracy of the results given by his/her technique. It is necessary to take special precautions, not only for reasons of hygiene, but also to ensure good reproducibility of the results. It is not possible to specify all the precautions to be taken in all circumstances, but this document at least provides the main measures to be taken when preparing, sterilizing and storing the media and the equipment.

The given recommendations will allow enumeration and detection of mesophilic microorganisms which may grow under aerobic conditions.

The recommendations are applicable to the determination of the absence of, or limited occurrence of specified microorganisms that are of interest for cosmetic products.

The test methods are described in the individual standards. Alternative microbiological procedures can be used provided that their equivalence has been demonstrated or the method has been otherwise demonstrated to be suitable. The choice of a specific method, or combination of methods mentioned in these International Standards will depend on the purpose for performing the test and it is for the user to decide which approach is best for his/her application.

INTERNATIONAL STANDARD **ISO 21148:2017(E)**

Cosmetics — Microbiology — General instructions for microbiological examination

1 Scope

This document gives general instructions for carrying out microbiological examinations of cosmetic products, in order to ensure their quality and safety, in accordance with an appropriate risk analysis (e.g. low water activity, hydro-alcoholic, extreme pH values).

Because of the large variety of products and potential uses within this field of application, these instructions might not be appropriate for some products in every detail (e.g. certain water-immiscible products).

2 Normative references

There are no normative references in this document.