

**Cosmetics - Microbiology - General instructions for
microbiological examination**

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 21148:2009 sisaldab Euroopa standardi EN ISO 21148:2009 ingliskeelset teksti.

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ICS 07.100.99; 71.100.70

English Version

Cosmetics - Microbiology - General instructions for microbiological examination (ISO 21148:2005)

Cosmétiques - Microbiologie - Instructions générales pour
les examens microbiologiques (ISO 21148:2005, Cor
1:2006 inclus)

Kosmetik - Mikrobiologie - Allgemeine Anleitungen für
mikrobiologische Untersuchungen (ISO 21148:2005)

This European Standard was approved by CEN on 23 May 2009.

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Foreword

The text of ISO 21148:2005 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 21148:2009 by Technical Committee CEN/SS H99 "Products for household and leisure use - Undetermined" the secretariat of which is held by CMC.

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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

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Endorsement notice

The text of ISO 21148:2005 has been approved by CEN as a EN ISO 21148:2009 without any modification.

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Introduction

The purpose of this International Standard 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 International Standard 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 International Standard 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 validated. 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.

Cosmetics — Microbiology — General instructions for microbiological examination

1 Scope

This International Standard 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 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

product

portion of an identified cosmetic product received in the laboratory for testing

2.2

sample

portion of the product (at least 1 g or 1 ml) which is used in the test to prepare the initial suspension

2.3

initial suspension

suspension (or solution) of a sample in a defined volume of an appropriate liquid (diluent, neutralizer, broth or combination of them)

2.4

sample dilution

dilution of the initial suspension

3 Premises

3.1 Test areas

The areas required for the specific operation of a microbiology laboratory are as follows:

- receipt, storage, preparation and processing of the samples;
- preparation and sterilization of culture media, apparatus and glassware;
- performance of analyses: weighing, dilutions, inoculations, subculturing, incubation, maintenance of the strain, etc.;
- decontamination and cleaning of apparatus, glassware, and processing of the analysis waste.