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

*Cosmétiques — Microbiologie — Instructions générales pour les
examens microbiologiques*



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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.

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 21148 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

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.

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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.