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Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

Cosmétiques — Microbiologie — Évaluation de la protection antimicrobienne d'un produit cosmétique

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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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For an explanation of 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 www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This second edition cancels and replaces the first edition (ISO 11930:2012), which has been technically revised. The main changes compared to the previous edition are as follows.

— Two types of diluents, composition 1 and composition 2 can be used as the diluents for bacteria and *Candida albicans* on the revised version (5.2.3).

— 5.6.2 Paragraph 2 has been changed to "When counts of surviving microorganisms obtained in 5.6.1.4 c) are less than 30 for bacteria and *C. albicans* or less than 15 for *A. brasiliensis* at the dilution where neutralization has been checked, record the number of colonies on Petri dishes and express results by multiplying by the dilution factor. If no colonies are observed at the dilution where neutralization has been checked, note the result as <1 and multiply by the dilution factor."

Introduction

This document is designed to be used in the overall evaluation of the antimicrobial protection of a cosmetic product.

The antimicrobial protection of a product can come from many sources:

— chemical preservation;

— inherent characteristics of the formulation;

— package design;

— manufacturing process.

This document defines a series of steps to be taken when assessing the overall antimicrobial protection of a cosmetic product. A reference method for a preservation efficacy test (challenge test) along with evaluation criteria is also described in this document.

The test described in this document involves, for each test microorganism, placing the formulation in contact with a calibrated inoculum, and then measuring the changes in the microorganism count at set time intervals for a set period and at a set temperature.

The data generated by the risk assessment (see ISO 29621) or by the preservation efficacy test, or both, are used to establish the level of antimicrobial protection required to minimize user risk.

Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

1 Scope

This document specifies a procedure for the interpretation of data generated by the preservation efficacy test or by the microbiological risk assessment, or both, when evaluating the overall antimicrobial protection of a cosmetic product.

It comprises:

— a preservation efficacy test;

— a procedure for evaluating the overall antimicrobial protection of a cosmetic product that is not considered low risk, based on a risk assessment described in ISO 29621.

The preservation efficacy test is a reference method to evaluate the preservation of a cosmetic formulation. It is applicable to cosmetic products in the marketplace.

This test does not apply to those cosmetic products for which the microbiological risk has been determined to be low according to Annex A and ISO 29621.

This test is primarily designed for water-soluble or water-miscible cosmetic products and can be used with modification to test products in which water is the internal (discontinuous) phase.

NOTE This test can be used as a guideline to establish a development method during the development cycle of cosmetic products. In this case, the test can be modified or extended, or both, for example, to make allowance for prior data and different variables (microbial strains, media, incubation conditions exposure time, etc.). Compliance criteria can be adapted to specific objectives. During the development stage of cosmetic products, other methods, where relevant, can be used to determine the preservation efficacy of formulations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*

ISO 18415, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

ISO 21148:2017, *Cosmetics — Microbiology — General instructions for microbiological examination*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 29621, *Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21148 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
cosmetic formulation
preparation of raw materials with a qualitatively and quantitatively defined composition

3.2
cosmetic product
cosmetic formulation (3.1) that has undergone all stages of production, including packaging in its final container

3.3
antimicrobial protection of a cosmetic product
ability of a *cosmetic product* (3.2) to overcome microbial contamination that might present a potential risk to the user or to the aesthetic and functional integrity of the product, during intended use

Note 1 to entry: The overall antimicrobial protection includes preservation of the formulation, the specific manufacturing process and protective packaging.

3.4
preservation of a cosmetic formulation
set of means used to avoid microbial proliferation in a *cosmetic formulation* (3.1)

EXAMPLE Preservatives, multifunctional compounds, hostile raw materials, extreme pH, low water-activity values.

3.5
reference method
method applied by interested parties to assess a product on the market and in case of dispute

3.6
development method
in-house method
method used during the development stage of a product before the product is put on the market

3.7
consumer
end user of a *cosmetic product* (3.2)

4 Principle

The evaluation of the antimicrobial protection of a cosmetic product combines the following elements (see Annex A).

a) The characteristics of its formulation (see ISO 29621) or the results of the preservation efficacy test (if performed), or both.

   The preservation efficacy test is described in Clause 5.

b) The characteristics of the cosmetic product in conjunction with the production conditions (see ISO 22716 and ISO 29621), the packaging materials and, if justified, recommendations for use of the product (see ISO 29621) and, when relevant, the area of application and the targeted user population (see Annex D).

This document describes a procedure for the interpretation of data generated by the preservation efficacy test (if appropriate) and by the microbiological risk assessment.

5 Preservation efficacy test

5.1 General

The evaluation of the preservation of a cosmetic formulation is based on inoculation of the formulation with calibrated inocula (prepared from relevant strains of microorganisms). The number of surviving microorganisms is measured at defined intervals during a period of 28 days. For each time and each strain, the log reduction value is calculated and compared to the minimum values required for evaluation criteria A or B (see Annex B).

When used as a reference method, procedures shall be strictly followed in order to avoid variability in results. To determine the preservation efficacy of a formulation during product development, other suitable development methods may be used.

Prior to the test, neutralizer efficacy shall be established (see 5.5), and the microbiological quality of the product shall be determined (in accordance with ISO 21149 and ISO 16212, or with ISO 18415) to ensure that any microorganisms present in the test sample do not interfere with recovery of test organisms.

5.2 Materials, apparatus, reagents and culture media

5.2.1 General

When water is used in diluents, neutralizers or culture media preparation, use distilled water or purified water as specified in ISO 21148:2017, 8.2.

5.2.2 Materials

In addition to the microbiology laboratory equipment described in ISO 21148, the following materials should be used

5.2.2.1 Glass beads, 3 mm to 4 mm in diameter.

5.2.2.2 Sintered glass filter, of porosity 2 (40 µm to 100 µm).

5.2.2.3 Sterile glass containers with closures, of suitable volumes.

5.2.2.4 Centrifuge, capable of a centrifugal force of 2 000*g*.

5.2.3 Diluents

5.2.3.1 General

Unless otherwise specified, all reagents shall be equilibrated at ambient temperature before use. When available, ready-to-use reagents and media may be used.

5.2.3.2 Diluents for bacteria and *Candida albicans*

5.2.3.2.1 Composition 1

Sodium chloride	8,5 g
Water	1 000 ml

5.2.3.2.2 Preparation

Dissolve sodium chloride in the water by mixing. Dispense into suitable containers. Sterilize in the autoclave at 121 °C for 15 min.

5.2.3.2.3 Composition 2

Tryptone pancreatic digest of casein	1,0 g
Sodium chloride	8,5 g
Water	1 000 ml

5.2.3.2.4 Preparation

Dissolve the components in the water by mixing while heating. Dispense into suitable containers. Sterilize in the autoclave at 121 °C for 15 min. After sterilization, the pH shall be equivalent to 7,0 ± 0,2, when measured at room temperature.

5.2.3.3 Diluent for preparation of *Aspergillus brasiliensis*: polysorbate solution

Prepare a solution of polysorbate 80 (0,5 g/l). Dissolve by mixing while heating until complete dissolution is achieved. Dispense the solution into suitable containers. Sterilize in the autoclave at 121 °C for 15 min.

5.2.4 Neutralizer

5.2.4.1 General

The suitability and effectiveness of the neutralizing agent with respect to the test strains used and to the tested formulation shall be demonstrated as specified in 5.5.

The neutralizer described in 5.2.4.2 is frequently used. Examples of other suitable neutralizers are given in Annex C (see Table C.1).

5.2.4.2 Eugon LT 100 liquid broth

5.2.4.2.1 General

This medium contains ingredients that neutralize inhibitory substances present in the sample (lecithin and polysorbate 80) and dispersing agent octoxynol 9 (Triton X100®[1]). It may be prepared as described in 5.2.4.2.2, or from dehydrated culture medium, according to the manufacturer's instructions. A ready-to-use medium may also be used.

5.2.4.2.2 Composition

Pancreatic digest of casein	15 g
Papaic digest of soybean meal	5 g
Sodium chloride	4 g
L-cystine	0,7 g

1) Triton X100® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

Sodium sulphite	0,2 g
Glucose	5,5 g
Egg lecithin	1 g
Polysorbate 80	5 g
Octoxynol 9	1 g
Water	1 000 ml

5.2.4.2.3 Preparation

Dissolve successively into boiling water polysorbate 80, octoxynol 9 and egg lecithin until they are completely dissolved. Dissolve the other components by mixing while heating. Dispense the medium into suitable containers. Sterilize in the autoclave at 121 °C for 15 min. Mix well after sterilization while the liquid is still hot to redissolve settled substances. After sterilization, the pH shall be equivalent to 7,0 ± 0,2 when measured at room temperature.

5.2.5 Culture media

5.2.5.1 General

Culture media may be prepared as in 5.2.5.2, 5.2.5.3 and 5.2.5.4, or from dehydrated culture media according to the manufacturer's instructions. Ready-to-use media may be used when their composition and/or growth yields are comparable to those of the formulae given in 5.2.5.2.1, 5.2.5.3.1 and 5.2.5.4.1.

5.2.5.2 Culture medium for bacteria: tryptic soy agar (TSA) or soybean casein digest agar medium

5.2.5.2.1 Composition

Pancreatic digest of casein	15,0 g
Papaic digest of soybean meal	5,0 g
Sodium chloride	5,0 g
Agar	15,0 g
Water	1 000 ml

5.2.5.2.2 Preparation

Dissolve the components or the dehydrated complete medium in the water by mixing while heating. Dispense the medium into suitable containers. Sterilize in the autoclave at 121 °C for 15 min. Mix well after sterilization while the liquid is still hot to redissolve settled substances. After sterilization and cooling down, the pH shall be equivalent to 7,3 ± 0,2 when measured at room temperature.