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Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products

Cosmétiques — Microbiologie — Lignes directrices pour l'appréciation du risque et l'identification de produits à faible risque microbiologique

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Contents

Page

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 29621 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This corrected version of ISO 29621:2010 incorporates the following corrections:

— in the last sentence of the first paragraph and the first sentence of the third paragraph of 3.2.3, the word intercellular has been replaced by intracellular;

— the first and second sentences of the fifth paragraph of 3.2.3 have been corrected so that the pH values are the same as in Table 2;

— in the third paragraph of 3.2.4, > has been replaced by ≥.

Introduction

Every cosmetic manufacturer has a dual responsibility relative to the microbiological quality of its products. The first is to ensure that the product, as purchased, is free from the numbers and types of microorganisms that could affect product quality and consumer health. The second is to ensure that microorganisms introduced during normal product use will not adversely affect the quality or safety of the product.

The first step would be to perform a microbiological risk assessment of the product to determine if the cosmetic microbiological International Standards apply.

Microbiological risk assessment is based on a number of factors generally accepted as important in evaluating the adverse effects on product quality and consumer health. It is intended as a guide in determining what level of testing, if any, is necessary to assure the quality of the product. Conducting a microbiological risk assessment involves professional judgment and/or a microbiological analysis, if necessary, to determine the level of risk.

The nature and frequency of testing vary according to the product. The significance of microorganisms in non-sterile cosmetic products should be evaluated in terms of the use of the product, the nature of the product and the potential harm to the user.

The degree of risk depends on the ability of a product to support the growth of microorganisms and on the probability that those microorganisms can cause harm to the user. Many cosmetic products provide optimum conditions for microbial growth, including water, nutrients, pH and other growth factors. In addition, the ambient temperatures and relative humidity at which many cosmetic products are manufactured, stored and used by consumers, will promote growth of mesophiles that could cause harm to users or cause degradation of the product. For these types of product, the quality of the finished goods is controlled by applying cosmetic good manufacturing practices (GMPs) (see ISO 22716) during the manufacturing process, using preservatives and conducting control tests using appropriate methods.

The likelihood of microbiological contamination for some cosmetic products is extremely low (or non-existent) due to product characteristics that create a hostile environment for survival/growth of microorganisms. These characteristics are elaborated in this International Standard. While the hazard (adverse effects on product quality and consumer health) may remain the same for these products, the likelihood of an occurrence is extremely low. Those products identified as “hostile” and produced in compliance with GMPs pose a very low overall risk to the user.

Therefore, products that comply with the characteristics outlined in this International Standard do not require routine microbiological testing.

The objective of these guidelines is to help cosmetic manufacturers and regulatory bodies to determine when, based on a “risk assessment,” the routine application of the microbiological International Standards for cosmetics and other relevant methods is not necessary.

Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products

1 Scope

The objective of this International Standard is to help cosmetic manufacturers and regulatory bodies define those finished products that, based on a risk assessment, present a low risk of microbial contamination during production and/or use, and therefore, do not require the application of microbiological International Standards for cosmetics.

2 Terms and definitions

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

2.1
risk
effect of uncertainty on objectives

[ISO Guide 73:2009, definition 1.1]

NOTE Microbiological risk is associated with the ability of a product to:

— support the growth of microorganisms and the probability that those microorganisms can cause harm to the user;

— support the presence of specified microorganisms as identified in cosmetic microbiological International Standards, e.g. ISO 18415, ISO 18416, ISO 22717, ISO 22718 and ISO 21150.

2.2
risk assessment
overall process of risk identification, **risk analysis** (2.3) and **risk evaluation** (2.4)

[ISO Guide 73:2009, definition 3.4.1]

2.3
risk analysis
process to comprehend the nature of **risk** (2.1) and to determine the level of risk

[ISO Guide 73:2009, definition 3.6.1]

2.4
risk evaluation
process of comparing the results of **risk analysis** (2.3) with **risk criteria** (2.5) to determine whether the **risk** (2.1) and/or its magnitude is acceptable or tolerable

[ISO Guide 73:2009, definition 3.7.1]

2.5
risk criteria
terms of reference against which the significance of a **risk** (2.1) is evaluated

[ISO Guide 73:2009, definition 3.3.1.3]

2.6
microbiologically low-risk products
products whose environment denies microorganisms the physical and chemical requirements for growth and/or survival

NOTE 1 This category of low-risk products applies to microbiological contamination which may occur during manufacturing and/or use by the consumer.

NOTE 2 A product whose packaging prevents the ingress of microorganisms is considered a microbiological low-risk product during its use.

NOTE 3 The inclusion of preservatives or other antimicrobial compounds in a formulation by itself would not constitute a low-risk product.

3 Risk assessment factors

3.1 General

A number of product characteristics needs to be evaluated when performing a microbial risk assessment, to determine if that product should be subject to the published microbiological International Standards for cosmetics or other relevant methods. These characteristics include the composition of the product, the production conditions, packaging and a combination of these factors.

3.2 Composition of the product

3.2.1 General characteristics

Products with certain physico-chemical characteristics do not allow the proliferation of microorganisms of concern to cosmetic products. Any number of physico-chemical factors or combinations thereof in a product can create a hostile environment that will not support microbial growth and/or survival. Combinations of sub-lethal factors will increase the hostility of the environment and increase the lag phase. If the environment is hostile enough, the lag phase will be extended to infinity and therefore cause cell death. Combinations of lethal factors will cause rapid cell death. The following factors should be considered in determining whether cosmetic products present a hostile environment.

3.2.2 Water activity, a_w, of formulation

Water is one of the most important factors controlling the rate of growth of an organism. It is not the total moisture content that determines the potential for growth but the available water in the formulation. The metabolism and reproduction of microorganisms demand the presence of water in an available form. The most useful measurement of water availability in a product formulation is water activity, a_w. Water activity is defined as the ratio of the water vapour pressure of the product to that of pure water at the same temperature:

$$a_w = \frac{p}{p_0} = \frac{n_2}{(n_1 + n_2)}$$

where

p is the vapour pressure of the solution;

p_0 is the vapour pressure of pure water;

n_1 is the number of moles of solute;

n_2 is the number of moles of water.

When a solution becomes more concentrated, vapour pressure decreases, and the water activity falls from a maximum of 1,00 (a_w for pure water). These conditions have been categorized with respect to their capacity to grow and produce metabolites in various conditions and values of a_w. The influence of reduced a_w on microorganisms is well documented. As the amount of free water in a formulation is reduced (decrease in a_w), the microorganism is faced with the challenge of maintaining a state of turgor within the cell. Loss of turgor will result in slower growth and eventually death of the cell. Many organisms survive under conditions of low a_w but will not grow. Lowered a_w causes an increase in the lag phase of growth, decrease in growth and decrease in total cell count. At very low values of a_w, it can be assumed that the lag phase becomes infinite, i.e. no growth. In low a_w environments, cells shall use energy to accumulate compatible solutes to maintain internal pressure. The growth of most bacteria is confined to an a_w above 0,90. Yeast and mould can grow at a much lower a_w with a limiting value above 0,60. See reference [1].

Listed below are examples of the minimum water activity levels required for growth of selected microorganisms.

Table 1 — Approximate minimum water activity, a_w, required for growth of selected microorganisms
(see reference [2])

Microorganism	a_w
Most bacteria	0,90
Pseudomonas species	0,96
Enterobacteriacae	0,93
Staphylococcus aureus	0,86
Most spoilage yeast	0,70
Most spoilage mould	0,60

The above water activity values should be considered as reference points, since microbial growth may occur at lower values depending on differences in temperature, pH or nutrient content of the product formulation. Even though water activity values are important in assisting in the risk analysis for microbial contamination, water activity should not be used as the sole indicator in determining whether product testing is necessary for a particular product formulation. Other factors such as manufacturing and filling temperatures should be taken into consideration to determine if a product requires further microbiological testing.

3.2.3 pH of formulation

The use of acidic pH is a common practice in the food industry for protection against bacteria and these same principles apply to cosmetics. The combination of acidic pH and a_w has been thoroughly studied (see reference [3]). In many instances, the level of inhibition on microbial activity depends on the specific acid being used. Acidic conditions around pH 5 favour mould and yeast proliferation but will not support bacterial growth. As the pH falls below pH 3,0, the conditions for growth of yeast become hostile (see reference [4]); this is because intracellular pH has to be maintained within relatively narrow limits.