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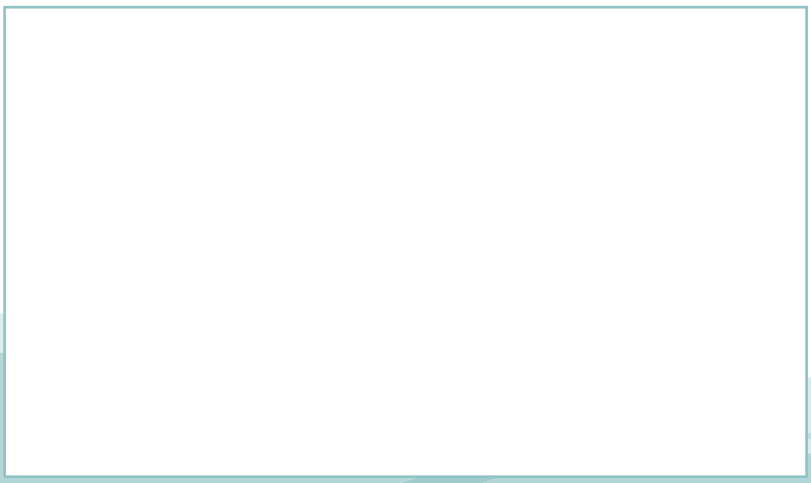
SWEDISH STANDARDS INSTITUTE

Kosmetika – Mikrobiologi – Vägledning för riskbedömning och identifiering av mikrobiologiska lågriskprodukter (ISO 29621:2017)

Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2017)



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Europastandarden EN ISO 29621:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 29621:2017.

Denna standard ersätter SS-EN ISO 29621:2011, utgåva 1.

The European Standard EN ISO 29621:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 29621:2017.

This standard supersedes the Swedish Standard SS-EN ISO 29621:2011, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Kosmetik samt analysmetoder för allergener, SIS/TK 495.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 29621

March 2017

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Supersedes EN ISO 29621:2011

English Version

Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2017)

Cosmétiques - Microbiologie - Lignes directrices pour l'appréciation du risque et l'identification de produits à faible risque microbiologique (ISO 29621:2017)

Kosmetische Mittel - Mikrobiologie - Leitlinien für die Risikobewertung und Identifikation von mikrobiologisch risikoarmen Produkten (ISO 29621:2017)

This European Standard was approved by CEN on 25 February 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 29621:2017) 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 September 2017, and conflicting national standards shall be withdrawn at the latest by September 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 29621:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 29621:2017 has been approved by CEN as EN ISO 29621:2017 without any modification.

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 is to 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 products, 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 document. 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. These 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 document do not require microbiological testing.

This document gives guidance to cosmetic manufacturers and regulatory bodies to determine when, based on a “risk assessment,” the 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

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

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
risk
effect of uncertainty on objectives

Note 1 to entry: 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.

[SOURCE: ISO Guide 73:2009, 1.1, modified]

3.2
risk assessment
overall process of risk identification, *risk analysis* (3.3) and *risk evaluation* (3.4)

[SOURCE: ISO Guide 73:2009, 3.4.1]

3.3
risk analysis
process to comprehend the nature of *risk* (3.1) and to determine the level of risk

[SOURCE: ISO Guide 73:2009, 3.6.1]

3.4
risk evaluation
process of comparing the results of *risk analysis* (3.3) with *risk criteria* (3.5) to determine whether the *risk* (3.1) and/or its magnitude is acceptable or tolerable

[SOURCE: ISO Guide 73:2009, 3.7.1]

3.5
risk criteria
term of reference against which the significance of a *risk* (3.1) is evaluated

[SOURCE: ISO Guide 73:2009, 3.3.1.3, modified]

3.6
microbiologically low-risk product
product whose environment denies microorganisms the physical and chemical requirements for growth and/or survival

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

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

Note 3 to entry: The inclusion of preservatives or other antimicrobial compounds in a formulation by itself would not necessarily constitute a low-risk product.

4 Risk assessment factors

4.1 General

A number of product characteristics needs to be evaluated when performing a microbial risk assessment to determine if that product should be subjected 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.

4.2 Composition of the product

4.2.1 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.

4.2.2 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 require 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 [see Formula (1)]:

$$a_w = \frac{p}{p_0} = \frac{n_2}{(n_1 + n_2)} \quad (1)$$

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. Some yeast and mould can grow at a much lower a_w with a limiting value above 0, 60 (see References [1] and [2]).

Listed in Table 1 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

Bacteria	Water activity (a_w)	Molds and yeast	Water activity (a_w)
Pseudomonas aeruginosa	0,97	*Rhizopus nigricans*	0,93
Bacillus cereus	0,95	*Mucor plumbeus*	0,92
Clostridium botulinum, Type A	0,95	*Rhodotorula mucilaginosa*	0,92
Escherichia coli	0,95	*Saccharomyces cerevisiae*	0,90
Clostridium perfringens	0,95	*Paecilomyces variotii*	0,84
Lactobacillus viridescens	0,95	*Penicillium chrysogenum*	0,83
Salmonella spp.	0,95	*Aspergillus fumigatus*	0,82
Enterobacter aerogenes	0,94	*Penicillium glabrum*	0,81
Bacillus subtilis	0,90	*Aspergillus flavus*	0,78
Micrococcus lysodeikticus	0,93	*Aspergillus brasiliensis*	0,77
Staphylococcus aureus (see Reference [2])	0,86	*Zygosaccharomyces rouxii* (osmophilic yeast)	0,62
Halobacterium halobium (halophilic bacterium)	0,75	*Xeromyces bisporus* (xerophilic fungi)	0,61

The water activity values in Table 1 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