Irish Standard
I.S. EN ISO 29621:2017

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

I.S. EN ISO 29621:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 29621:2017 is the adopted Irish version of the European Document EN ISO 29621:2017, Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2017)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 29621

March 2017

ICS 07.100.40

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.

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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of an identical text or by endorsement, at the latest by September 2017, and conflicting national standards shall be withdrawn at the latest by September 2017.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.

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Endorsement notice

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

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I.S. EN ISO 29621:2017

INTERNATIONAL STANDARD

ISO 29621

Second edition
2017-03

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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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 on the voluntary nature of ISO 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 29621:2010), which has been technically revised.

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]