SLOVENSKI STANDARD
SIST EN ISO 29621:2011

01-april-2011

Kozmetika - Mikrobiologija - Smernice za oceno tveganja in prepoznavanja izdelkov, ki ne predstavljajo večjega mikrobiološkega tveganja (ISO 29621:2010)

Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2010)

Kosmetische Mittel - Mikrobiologie - Leitlinien für die Bewertung und Identifikation von mikrobiologisch risikoarmen Produkten (ISO 29621:2010)

Cosmétiques - Microbiologie - Lignes directrices pour l'appréciation du risque et l'identification de produits à faible risque microbiologique (ISO 29621:2010)

Ta slovenski standard je istoveten z: **EN ISO 29621:2011**

ICS:

07.100.40	Kozmetika - mikrobiologija	Cosmetics microbiology
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

SIST EN ISO 29621:2011 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 29621

January 2011

ICS 07.100.99; 71.100.70

English Version

Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2010)

Cosmétiques - Microbiologie - Lignes directrices pour l'appréciation du risque et l'identification de produits à faible risque microbiologique (ISO 29621:2010)

Kosmetische Mittel - Mikrobiologie - Leitlinien für die Risikobewertung und Identifikation von mikrobiologisch risikoarmen Produkten (ISO 29621:2010)

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Foreword

The text of ISO 29621:2010 has been prepared by Technical Committee ISO/TC 217 “Cosmetics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 29621:2011 by Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by July 2011, and conflicting national standards shall be withdrawn at the latest by July 2011.

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Endorsement notice

The text of ISO 29621:2010 has been approved by CEN as a EN ISO 29621:2011 without any modification.

INTERNATIONAL STANDARD

ISO 29621

First edition
2010-06-01

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

Reference number
ISO 29621:2010(E)

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Published in Switzerland

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Foreword

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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.

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

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.

