SLOVENSKI STANDARD
oSIST ISO/DIS 29621:2009

01-junij-2009

Kozmetika - Mikrobiologija - Smernice za oceno tveganja in prepoznavanja izdelkov, ki ne predstavljajo veļ jega mikrobiologķega tveganja

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

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

Ta slovenski standard je istoveten z: **ISO/DIS 29621**

ICS:

07.100.99	Drugi standardi v zvezi z mikrobiologijo	Other standards related to microbiology
71.100.70	Kozmetika. Toaletni pripomoļ ki	Cosmetics. Toiletries

oSIST ISO/DIS 29621:2009 **en,fr**

DRAFT INTERNATIONAL STANDARD ISO/DIS 29621

ISO/TC **217** Secretariat: **ISIRI**

Voting begins on: **2008-09-22** Voting terminates on: **2009-02-22**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

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ICS 07.100.99; 71.100.70

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Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

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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*.

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 ISO 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 and the significance of micro-organisms 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 products, the quality of the finished goods are controlled by applying cosmetic GMPs (see ISO 22716) during the manufacturing process, use of 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. Those products identified as "hostile" and produced in compliance with GMPs pose a very low overall risk to the user.

Therefore, products which comply with the characteristics outlined in this document do not require routine microbiological testing.

The objective of this guideline is to help cosmetic manufacturers and regulatory bodies to determine when, based on a "risk assessment," the routine application of the ISO Microbiological Standards and other relevant methods are not necessary.

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

1 Scope

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk assessment so as to determine the types of cosmetic products to which the microbiology standards apply. The objective of this guideline is to define those finished products which present a low risk of microbial contamination during production and/or use, and therefore, do not require the application of the ISO microbiological cosmetic standards.

2 Terms and Definitions

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

2.1

risk

Combination of the probability of an event and it's consequence (ISO Guideline 73 2002)

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

- Support the growth of micro organisms and the probability that those micro organisms can cause harm to the user.
- Support the presence of specified micro organisms as identified in ISO Cosmetic Microbiological Standards - 18415, 18416, 22717, 22718, 21150.

2.2

risk assessment

Overall process of risk analysis and risk evaluation (ISO Guide73 2002)

2.3

risk analysis

Systematic use of information to identify sources and to estimate the risk (ISO Guide73 2002)

2.4

risk evaluation

Process of comparing the estimated risk against given risk criteria to determine the significance of the risk.

2.5

risk criteria

Terms of reference by which the significance of risk is assessed. (ISO Guide73 2002)

2.6

low microbiological risk products

Products whose environment denies microorganisms the physical and chemical requirements for growth and /or survival. This category of low risk products applies to microbiological contamination which may occur during manufacturing and/or use by the consumer.

2.6.1 A product whose composition denies microorganisms the physical and chemical requirements for growth and /or survival is considered microbiological low-risk products for both production and use.

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

3 Risk Assessment Factors

3.1 General

A number of product characteristics need to be evaluated when performing a microbial risk assessment to determine if that product should be subject to the published ISO microbiological quality standards or other relevant methods. These characteristics include the composition of the product, the production conditions and the packaging.

3.2 Composition of the product

Products with certain physico-chemical characteristics do not allow the proliferation of microorganisms of concern to cosmetic products. Any number of physiochemical 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.

3.2.1 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 demands 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 vapor pressure of the product to that of pure water at the same temperature:

$a_w = p/po = [n2/(n1 + n2)]$.

Where,

p is the vapor pressure of the solution,

po is the vapor pressure of pure water,