Singapore Standards Council

SS ISO 11930 : 2017
ISO 11930 : 2012, IDT
(ICS 07.100.40)

SINGAPORE STANDARD

Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

Published by
Enterprise Singapore

SS ISO 11930 : 2017
ISO 11930 : 2012, IDT
(ICS 07.100.40)

SINGAPORE STANDARD

Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

ISBN 978-981-47-8405-4

This Singapore Standard was approved by the Biomedical Standards Committee on behalf of the Singapore Standards Council on 28 April 2017.

First published, 2017

The Biomedical Standards Committee, appointed by the Standards Council, consists of the following members:

		Name	Capacity
Acting Chairman	:	Mr Foo Yang Tong	*Individual Capacity*
Advisor		Ms Jacqueline Monteiro	*Individual Capacity*
Secretary	:	Mr Choi Kwok Keong	*Singapore Manufacturing Federation – Standards Development Organisation*
Members	:	Mr David Barda	*Exploit Technologies Pte Ltd*
		Prof Kishore Bhakoo	*Singapore Bioimaging Consortium*
		Ms Sheryl Chen	*Economic Development Board*
		Mr Chung Kwong Yuew	*Temasek Polytechnic*
		Ms Farah Binte Mohamed Haniff	*National Healthcare Group Pte Ltd*
		Prof James Goh	*Biomedical Engineering Society (Singapore)*
		Dr Stuart Koe	*Singapore Manufacturing Federation*
		Ms Evelyn Koh	*Ministry of Manpower*
		Mr Kwan Fook Weng	*Singapore Health Services Pte Ltd*
		Ms Kwek Puay Ee	*Singapore Nursing Board*
		Assoc Prof Leo Hwa Liang	*National University of Singapore (Biomedical Engineering)*
		Dr Leonard Loh	*Nanyang Polytechnic*
		Assoc Prof Eddie Ng Yin Kwee	*Nanyang Technological University*
		Dr Ong Siew Hwa	*Individual Capacity*
		Mr Justin Phoon	*Biomedical Research Council*
		Mr Poo Yi Hong	*International Enterprise Singapore*
		Ms Celine Tan	*SPRING Singapore*
		Ms Jocelyn Yen	*Singapore Manufacturing Federation*
		Dr Yong Chern Chet	*Individual Capacity*

The Working Group on Cosmetics, appointed by the Biomedical Standards Committee to assist in the preparation of this standard, comprises the following experts who contribute in their *individual capacity*:

		Name
Convenor	:	Dr Alain Khaiat
Secretary	:	Ms Cynthia Toh Sook Ai
Members	:	Dr Maria Antipina
		Ms Stephanie Chan
		Dr Cheah Nuan Ping
		Ms Innocentia M Krisnawati

Members : Dr Khoo Keng Meng
Mr Lam Kok Seng
Dr Celine Valeria Liew
Mr Mohanram Subramaniam
Mr Pang Tit Keong
Ms Josephine Song
Mrs Marie Tham
Mr Gary Yao

The organisations in which the experts of the Working Group are involved are:

Arch Chemicals Singapore Pte Ltd
Celblos Dermal Research Centre Pte Ltd
Cosmetics, Toiletry and Fragrance Association of Singapore
Health Sciences Authority
Institute of Materials Research and Engineering
Johnson and Johnson Pte Ltd
Lubrizol Southeast Asia Pte Ltd
National University of Singapore
Procter & Gamble (S) Pte Ltd
SC Solution Pte Ltd
Singapore Polytechnic

(blank page)

Contents

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on Cosmetics under the direction of the Biomedical Standards Committee. This Singapore Standard is an identical adoption of International Standard ISO 11930:2012 “Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product” published by the International Organization for Standardization.

Attention is drawn to the following:

1. Where appropriate, the words ‘International Standard’ shall be read as ‘Singapore Standard’. The reference to ‘ISO 29621’ shall be replaced by ‘SS ISO 29621’.

2. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

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 11930 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This corrected version of ISO 11930:2012 incorporates the following correction:

— in Table B.1, in the Criteria A row, final column (T28), the words "and NI" have been added.

Introduction

This International Standard is to be used in the overall evaluation of the antimicrobial protection of a cosmetic product.

The antimicrobial protection of a product can come from many sources:

— chemical preservation;

— inherent characteristics of the formulation;

— package design;

— manufacturing process.

This International Standard defines a series of steps to be taken when assessing the overall antimicrobial protection of a cosmetic product. A reference method for a preservation efficacy test (challenge test) along with evaluation criteria is also described in this International Standard.

The data generated by the risk assessment (see ISO 29621) or by the preservation efficacy test, or both, are to be used to establish the level of antimicrobial protection required to minimize user risk.

Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product

1 Scope

1.1 General

This International Standard comprises:

— a preservation efficacy test;

— a procedure for evaluating the overall antimicrobial protection of a cosmetic product which is not considered low risk, based on a risk assessment described in ISO 29621.

This International Standard provides a procedure for the interpretation of data generated by the preservation efficacy test or by the microbiological risk assessment, or both.

1.2 Preservation efficacy test

This test is a reference method that is to be used to evaluate the preservation of a cosmetic formulation. It applies to cosmetic products in the market place.

This test is not required for those cosmetic products for which the microbiological risk has been determined to be low (see Annex A and ISO 29621).

This test is primarily designed for water-soluble or water-miscible cosmetic products and can require adaptation, for example to test products in which water is the internal phase. The test described in this International Standard involves, for each test micro-organism, placing the formulation in contact with a calibrated inoculum, and then measuring the changes in the micro-organism count at set time intervals for a set period and at a set temperature.

NOTE This test can be used as a guideline to develop an in-house method during the development cycle of cosmetic products. In this case, the test can be modified or extended, or both, for example to make allowance for prior data and different variables (microbial strains, media, incubation conditions exposure time, etc.). Compliance criteria can be adapted to specific objectives. During the development stage of cosmetic products, other methods, where relevant, can be used to determine the preservation efficacy of formulations.

1.3 Procedure for evaluating the antimicrobial protection of the cosmetic product

This procedure is based on careful consideration of the following points.

— Results of the preservation efficacy test. Not all cosmetic products will require a preservation efficacy test (see Annex A and ISO 29621).

— Formulation characteristics and data provided by the microbiological risk assessment (see ISO 29621). The analysis of the microbiological risk assessment is based on an overall approach. In particular, it integrates variables such as characteristics and composition of the formulation, its production conditions, the characteristics of the packaging in which the formulation will be delivered to the market place, recommendations for use of the cosmetic product and, when relevant, the area of application and the targeted user population (see Annex D).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*

ISO 18415, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 22716, *Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices*

ISO 29621, *Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products*