

SS ISO 21322 : 2020
ISO 21322:2020, IDT
(ICS 07.100.40)

SINGAPORE STANDARD

**Cosmetics — Microbiology — Testing of
impregnated or coated wipes and masks**



SS ISO 21322 : 2020

ISO 21322:2020, IDT
(ICS 07.100.40)

SINGAPORE STANDARD

**Cosmetics – Microbiology – Testing of impregnated
or coated wipes and masks**

Published by Enterprise Singapore

All rights reserved. Unless otherwise specified, no part of this Singapore Standard may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying and microfilming, without permission in writing from Enterprise Singapore. Request for permission can be sent to: standards@enterprisesg.gov.sg.

© ISO 2020 – All rights reserved
© Enterprise Singapore 2020

ISBN 978-981-49-2504-4

The content of this Singapore Standard was approved on 8 July 2020 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

First published, 2020

BHSC consists of the following members:

	Name	Representation
Chairman	: Dr Yong Chern Chet	<i>Individual Capacity</i>
Deputy Chairmen	: Mr Vincent Cheung Ms Selina Seah Ms Wong Woei Jiuang	<i>Individual Capacity</i> <i>Changi General Hospital</i> <i>Health Sciences Authority</i>
Advisor	: Ms Jacqueline Monteiro	<i>Individual Capacity</i>
Secretary	: Mr Kevin Tan	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
Members	: Mr Alec Chow Boon Kuan Mr Chung Kwong Yuew Ms Heidi Goh Prof James Goh Dr Lai Choon Sheen Dr Christopher Lam Assoc Prof Leo Hwa Liang Dr Lin Jianhua Dr Leonard Loh Ms Audrey Lok Assoc Prof Eddie Ng Yin Kwee Dr Ong Siew Hwa Dr Padmanabhan Saravanan Mr Peh Ruey Feng Prof Tan Puay Hoon Ms Wang Dan Dr Sidney Yee Dr Zhou Zhihong	<i>Medtronic International Ltd</i> <i>Temasek Polytechnic (BioMedical Engineering Faculty)</i> <i>Singapore Manufacturing Federation (Medical Technology Industry Group)</i> <i>Biomedical Engineering Society (Singapore)</i> <i>Eu Yan Sang International Ltd</i> <i>Health Sciences Authority</i> <i>National University of Singapore</i> <i>TÜV SÜD PSB Pte Ltd</i> <i>Nanyang Polytechnic</i> <i>Enterprise Singapore</i> <i>Nanyang Technological University</i> <i>Acumen Research Laboratories Pte Ltd</i> <i>Temasek Polytechnic (Centre of Innovation for Complementary Health Products)</i> <i>Individual Capacity</i> <i>Singapore Health Services Pte Ltd</i> <i>Biosensors International Group</i> <i>Diagnostics Development Hub – Accelerate Technologies Pte Ltd</i> <i>Singapore Bioimaging Consortium</i>

BHSC set up the Technical Committee on Laboratory Testing to oversee the preparation of this standard. The Technical Committee consists of the following members:

	Name	Representation
Chairman	: Dr Lin Jianhua	<i>Individual Capacity</i>
Secretary	: Mr Kevin Tan	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
Members	: Dr Eddie Ang Han San	<i>Singapore Association of Medical Laboratory Sciences</i>
	Dr Emily Cheah	<i>Charles River Laboratories Singapore</i>
	Prof Ding Jeak Ling	<i>National University of Singapore</i>
	Dr Lee Yun Hwa	<i>Temasek Polytechnic</i>
	Dr Thomas Li	<i>Diagnostics Development Hub – Accelerate Technologies Pte Ltd</i>
	Dr Ng Bee Ling	<i>Ministry of Home Affairs</i>
	Dr Oh Hue Kian	<i>Ministry of Home Affairs</i>
	Mr Alvin Sim Chee Yong	<i>Parkway Laboratory Services</i>
	Dr Sun Cuilian	<i>Health Sciences Authority</i>
	Dr Teh Boon King	<i>Vela Diagnostics</i>
	Ms Jessie Tong Yoke Ling	<i>Singapore Polytechnic (Consumer Chemicals Technology Centre)</i>
	Dr Woo Wee Hong	<i>Singapore Polytechnic (School of Chemical & Life Sciences)</i>
	Dr Adrian Yeo	<i>Singapore Polytechnic (School of Chemical & Life Sciences)</i>

The Technical Committee set up the National Mirror Working Group on ISO/TC 217 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

	Name
Convenor	: Dr Alain Khaiat
Deputy Convenor	: Mrs Marie Tham
Secretary	: Mr She Long Huai
Members	: Dr Maria Antipina
	Ms Stephanie Chan
	Dr Cheah Nuan Ping
	Dr Khoo Keng Meng
	Ms Innocentia M Krisnawati
	Mr Lam Kok Seng
	Ms Le Chau Giang
	Dr Celine Valeria Liew

Dr Nicole Ling
Mr Pang Tit Keong
Ms Bandana Seesurn
Ms Josephine Song
Mr Gary Yao

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

Agency for Science, Technology and Research
Celblos Dermal Research Centre Pte Ltd
Centre International De Developpement Pharmaceutique (CIDP) Pte Ltd
Cosmetic, Toiletry & Fragrance Association of Singapore (CTFAS)
Estée Lauder Companies
Health Sciences Authority
Johnson and Johnson Pte Ltd
Lonza Microbial Control Asia Pacific Pte Ltd
Lubrizol Southeast Asia Pte Ltd
National University of Singapore
Procter & Gamble
SC Solution Pte Ltd
Singapore Polytechnic

Contents

	Page
National Foreword	8
Foreword	9
Introduction	10
1 Scope	11
2 Normative references	11
3 Terms and definitions	11
4 Principle	12
4.1 General information	12
4.2 Selection of the test sample	13
4.3 Selection of the method	13
4.4 Recovery of microorganisms from the test sample	13
4.5 Enumeration of aerobic mesophilic microorganisms	13
4.5.1 General	13
4.5.2 Plate count method overview	13
4.5.3 Membrane filtration method overview	14
4.6 Detection of specified microorganisms by enrichment method	14
5 Diluents, neutralizers and culture media	14
5.1 General	14
5.2 Diluents and neutralizers	14
5.3 Culture media	14
5.3.1 Media for enumeration and detection	14
5.3.2 Media for preparation of spores of <i>Bacillus subtilis</i>	15
6 Apparatus and glassware	15
7 Strains of microorganisms	15
8 Handling of cosmetic products and laboratory samples	15
9 Procedure	15
9.1 General recommendation	15
9.2 Selection and preparation of the test sample	16
9.2.1 Selection of the test sample	16
9.2.2 Preparation of the initial suspension	16
9.3 Recovery of microorganisms	16
9.3.1 General	16
9.3.2 Stomaching	16

9.3.3	Shaking/Stirring.....	16
9.4	Enumeration of aerobic mesophilic microorganisms.....	17
9.4.1	General.....	17
9.4.2	Pour plate method.....	17
9.4.3	Surface spread method.....	17
9.4.4	Membrane filtration method.....	18
9.4.5	Incubation.....	18
9.4.6	Counting of colonies.....	18
9.5	Detection of specified microorganisms by enrichment method.....	18
9.5.1	General.....	18
9.5.2	Test for specified microorganisms.....	19
10	Expression of results.....	19
10.1	Enumeration of aerobic mesophilic microorganisms.....	19
10.2	Detection of specified microorganisms.....	19
11	Suitability test.....	20
12	Test report.....	20
Annex A (normative) Guidance on methods for microbiological testing of impregnated or coated products — Wipes and masks.....		
A.1	Selection of the test sample.....	21
A.2	Selection of the enumeration method for aerobic mesophilic microorganisms.....	21
Figure A.1 — Flow chart for the choice of plate count method.....		
A.3	Recovery of microorganisms.....	22
A.4	Summary of procedure for microbiological control of wipes and masks.....	23
Figure A.2 — Testing flow.....		
Annex B (informative) Expression and interpretation of results.....		
B.1	Counting and expression of results.....	25
B.2	Examples of expression of results — Plate count: Pour plate method.....	27
B.2.1	Treatment of the test sample.....	27
B.2.2	Single dose eye masks — Test sample 1 unit.....	27
B.2.3	Pack of wipes — Test sample 1/5 of a unit (test sample was a large towelette and therefore 1/5 of the towelette was weighed and tested).....	27
B.2.4	Single dose face mask — Test sample 1/2 unit.....	28
B.2.5	Single dose eyes mask — Test sample 2 units (1 unit is less than 1 g).....	28
B.2.6	Single dose face mask — Test sample 1 unit.....	29
B.3	Examples of expression of results — Plate count membrane filtration method.....	29
B.3.1	Treatment of the test sample.....	29
B.3.2	Pack of wipes — Test sample 1 unit.....	29

B.3.3	Single dose face mask — Test sample — 1/2 unit.....	30
B.3.4	Single dose eyes mask — Test sample 2 units — Each unit is less than 1 g.....	30
B.3.5	Single dose face mask — Test sample 1 unit	30
B.3.6	Single dose face mask — Test sample 1/2 unit.....	31
Annex C (normative)	Suitability test method.....	32
C.1	Preparation of inoculum	32
C.1.1	Bacteria.....	32
C.1.2	<i>Candida albicans</i>	32
C.1.3	Preparation of spores of <i>Bacillus subtilis</i>	32
C.1.3.1	Culture media.....	32
C.1.3.1.1	Tryptic soy agar (TSA) or soybean casein digest agar (SCDA).....	32
C.1.3.1.2	Peptone glucose agar with meat and yeast extract	32
C.1.3.1.3	Nutrient agar with 0,3 % of manganese (II) sulfate.....	33
C.1.3.1.4	Peptone and meat extract agar with sodium chloride	33
C.1.3.2	Preparation of spores stock suspension.....	33
C.2	Bioburden recovery	34
C.3	Neutralization of the antimicrobial properties of the product	35
C.3.1	General	35
C.3.2	Enumeration method.....	35
C.3.3	Enrichment method	35
C.4	Expression of results.....	35
C.4.1	Bioburden recovery	35
C.4.2	Neutralization of the antimicrobial properties of the product	36
C.4.2.1	Enumeration method.....	36
C.4.2.2	Enrichment method	36
Bibliography	37

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on ISO/TC 217 set up by the Technical Committee on Laboratory Testing under the purview of BHSC.

This standard is identical with ISO 21322:2020 “Cosmetics — Microbiology — Testing of impregnated or coated wipes and masks”, published by the International Organization for Standardization

NOTE 1 – Reference to International Standards are replaced by applicable Singapore Standards/Technical References.

NOTE 2 – Where numerical values are expressed as decimals, the comma is read as a full point.

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. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as “Mature standards”. Mature Standards will not be subject to further review, unless there are requests to review such standards.*
- 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 and the Singapore Standards Council 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. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*
- 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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of 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 www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

For technical reasons, current standards in cosmetics microbiology may not be applicable to impregnated or coated cosmetic products, such as wipes and masks, in which there is no direct access to the formulation.

Based on their product form or delivery there is a need to adapt these standards to assess the microbiological quality of these products.

Cosmetics — Microbiology — Testing of impregnated or coated wipes and masks

1 Scope

This document gives guidance for the enumeration and/or detection of microorganisms present in a cosmetic product that is impregnated or coated onto a substrate (i.e. wipes and masks) where sampling and microbiological influence of the manufactured product presents particular challenges in terms of microbiological sampling and testing.

The principle of this document can also be applied to test similar products (e.g. cushion, impregnated sponge, etc.) or applicators (e.g. brush, puff, sponge, etc.) with modification of the procedure as appropriate.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11930, *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*

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

ISO 18416, *Cosmetics — Microbiology — Detection of *Candida albicans**

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

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

ISO 21150, *Cosmetics — Microbiology — Detection of *Escherichia coli**

ISO 22717, *Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa**

ISO 22718, *Cosmetics — Microbiology — Detection of *Staphylococcus aureus**