## STN

#### Kozmetické výrobky Mikrobiológia Skúšanie impregnovaných alebo potiahnutých obrúskov a masiek (ISO 21322: 2020)

STN EN ISO 21322

68 1515

Cosmetics - Microbiology - Testing of impregnated or coated wipes and masks (ISO 21322:2020)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/22

Obsahuje: EN ISO 21322:2021, ISO 21322:2020

### EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

**EN ISO 21322** 

December 2021

ICS 07.100.40

#### **English Version**

## Cosmetics - Microbiology - Testing of impregnated or coated wipes and masks (ISO 21322:2020)

Cosmétiques - Microbiologie - Essais sur lingettes et masques imprégnés ou enduits (ISO 21322:2020)

Kosmetische Mittel - Mikrobiologie - Prüfung von getränkten oder beschichteten Reinigungstüchern und Masken (ISO 21322:2020)

This European Standard was approved by CEN on 5 December 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

#### EN ISO 21322:2021 (E)

Contents	Page
European foreword	3

EN ISO 21322:2021 (E)

#### **European foreword**

The text of ISO 21322:2020 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 21322:2021 by 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 June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

#### **Endorsement notice**

The text of ISO 21322:2020 has been approved by CEN as EN ISO 21322:2021 without any modification.

## INTERNATIONAL STANDARD

ISO 21322

First edition 2020-06

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

Cosmétiques — Microbiologie — Essais sur lingettes et masques imprégnés ou enduits





#### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Fax: +41 22 749 09 47 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Cor	itents	5	Page
Fore	word		v
Intro	duction	1	vi
1	Scope	3	1
2	Norm	ative references	1
3		s and definitions	
4	4.1 4.2 4.3 4.4 4.5	General information Selection of the test sample Selection of the method Recovery of microorganisms from the test sample Enumeration of aerobic mesophilic microorganisms 4.5.1 General 4.5.2 Plate count method overview 4.5.3 Membrane filtration method overview	
	4.6	Detection of specified microorganisms by enrichment method	
5	5.1 5.2 5.3	nts, neutralizers and culture media General Diluents and neutralizers Culture media 5.3.1 Media for enumeration and detection 5.3.2 Media for preparation of spores of <i>Bacillus subtilis</i>	
6	Appa	ratus and glassware	4
7	Strair	ns of microorganisms	4
8		ling of cosmetic products and laboratory samples	
		edure	
9	9.1 9.2	General recommendation Selection and preparation of the test sample 9.2.1 Selection of the test sample 9.2.2 Preparation of the initial suspension	5 5 5 5
	9.3	Recovery of microorganisms 9.3.1 General 9.3.2 Stomaching 9.3.3 Shaking/Stirring	6 6
	9.4	Enumeration of aerobic mesophilic microorganisms  9.4.1 General  9.4.2 Pour plate method  9.4.3 Surface spread method  9.4.4 Membrane filtration method  9.4.5 Incubation  9.4.6 Counting of colonies	
	9.5	Detection of specified microorganisms by enrichment method 9.5.1 General 9.5.2 Test for specified microorganisms	 8
10	Expression of results		9
	10.1 10.2	Enumeration of aerobic mesophilic microorganisms  Detection of specified microorganisms	9
11	Suita	bility test	9
12	Test r	eport	9

Annex A (normative) Guidance on methods for microbiological testing of impregnated or	
coated products — Wipes and masks	10
Annex B (informative) Expression and interpretation of results	14
Annex C (normative) Suitability test method	21
Bihliography	26

#### 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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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 <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

#### 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
```

#### koniec náhľadu – text ďalej pokračuje v platenej verzii STN