BS EN ISO 21149:2017+A1:2022

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

BSI Standards Publication

Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

National foreword

This British Standard is the UK implementation of EN ISO 21149:2017+A1:2022. It is identical to ISO 21149:2017, incorporating amendment 1:2022. It supersedes BS EN ISO 21149:2009, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by ▌A1⟩ ⟨A1▌.

The UK participation in its preparation was entrusted to Technical Committee CW/217, Cosmetics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 19501 9

ICS 07.100.40; 07.100.99; 71.100.70

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2017.

Amendments/corrigenda issued since publication

Date	Text affected
31 October 2022	Implementation of ISO amendment 1:2022 with CEN endorsement A1:2022

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21149+A1

September 2022

ICS 71.100.70; 07.100.99

Supersedes EN ISO 21149:2009

English Version

Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2017)

Cosmétiques - Microbiologie - Dénombrement et détection des bactéries aérobies mésophiles (ISO 21149:2017)

Kosmetische Mittel - Mikrobiologie - Zählung und Nachweis von aeroben mesophilen Bakterien (ISO 21149:2017)

This European Standard was approved by CEN on 26 April 2017.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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: Avenue Marnix 17, B-1000 Brussels

© 2017 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 21149:2017 E

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

European foreword

This document (EN ISO 21149:2017) has been prepared by Technical Committee ISO/TC 217 “Cosmetics” in collaboration with 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 December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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.

This document supersedes EN ISO 21149:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21149:2017 has been approved by CEN as EN ISO 21149:2017 without any modification.

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

European foreword to Amendment 1

This document (EN ISO 21149:2017/A1:2022) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by AFNOR.

This Amendment to the European Standard EN ISO 21149:2017 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 2023.

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/national committee. 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, Türkiye and the United Kingdom.

Endorsement notice to Amendment 1

The text of ISO 21149:2017/Amd 1:2022 has been approved by CEN as EN ISO 21149:2017/A1:2022 without any modification.

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

This page is left deliberately blank.

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

Contents

Page

Foreword ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Principle **2**
4.1 General 2
4.2 Plate count 2
4.3 Membrane filtration 2
4.4 Detection of bacteria by enrichment 3

5 Diluents, neutralizers and culture media **3**
5.1 General 3
5.2 Neutralizing diluents and diluents 3
5.3 Diluent for the bacterial suspension (tryptone sodium chloride solution) 4
5.4 Culture media 4

6 Apparatus and glassware **7**

7 Strains of microorganisms **7**

8 Handling of cosmetic products and laboratory samples **7**

9 Procedure **7**
9.1 General recommendation 7
9.2 Preparation of the initial suspension 7
9.2.1 General 7
9.2.2 Water-miscible products 8
9.2.3 Water-immiscible products 8
9.3 Counting methods 8
9.3.1 Dilutions for counting methods 8
9.3.2 Plate-count methods 8
9.4 Enrichment 9
9.4.1 General 9
9.4.2 Incubation of the sample 9

10 Counting of colonies (plate counts and membrane filtration methods) **9**

11 Detection of growth (enrichment method) **9**

12 Expression of results **10**
12.1 Method of calculation for plate count 10
12.2 Interpretation 11
12.3 Examples 11
12.4 Detection after enrichment 13

13 Neutralization of the antimicrobial properties of the product **13**
13.1 General 13
13.2 Preparation of inoculum 14
13.3 Suitability of counting methods 14
13.3.1 Principle 14
13.3.2 Suitability test of the pour-plate method 14
13.3.3 Suitability of the surface spread method 14
13.3.4 Suitability of the membrane filtration method 14
13.4 Suitability of the detection method by enrichment 15
13.4.1 Procedure 15
13.4.2 Interpretation of results 15
13.5 Interpretation of suitability test results 15

14 Test report **16**

© ISO 2017 – All rights reserved

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

Annex A (informative) **Other neutralizing diluents** **17**
Annex B (informative) **Other diluents** **19**
Annex C (informative) **Other culture media** **20**
Annex D (informative) **Neutralizers of antimicrobial activity of preservatives and rinsing liquids** **23**
Bibliography **24**

© ISO 2017 – All rights reserved

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21149:2006), of which it constitutes a minor revision with the following changes:

— in the Scope, "validated" has been changed to "shown to be suitable";

— in the Scope, "see ISO 29621" has been added and the reference has been added to the Bibliography;

— in 4.1, "validated" has been changed to "demonstrated";

— in 4.3, "validated" has been changed to "described";

— in 5.1, "specifications" has been changed to "instructions";

— in 9.3.2.1, 9.3.2.2 and 9.3.2.3, "validated" has been changed to "described";

— in 9.3.2.3, "procedure developed during the validation" has been changed to "suitability test procedure";

— in 9.4.1, "validation" has been changed to "suitability test";

— in 12.2.1, "validated according to the chosen method" has been changed to "demonstrated to be suitable for the chosen method";

— in 13.3 and 13.4, "validation" has been changed to "suitability";

— in 13.3.2, 13.3.3 and 13.3.4, "validation" has been changed to "suitability";

— in 13.3.2, 13.3.3 and 13.3.4, "if the validation count is at least 50 % (0,3 log) of the control count" has been changed to "if the count is at least 50 % of the control";

— in 13.4.1, instances of "validation test" have been changed to "suitability test";

© ISO 2017 – All rights reserved

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

— in 13.4.2, instances of “validation plate” have been changed to “suitability test plate”;

— in 13.5, “validation results” has been changed to “suitability test results” and “validation plates” has been changed to “suitability test plates”;

— in Clause 14 f), “validation of the method” has been changed to “demonstration of the suitability”;

— in A.1, B.1 and C.1, “validated” has been changed to “demonstrated to be suitable”.

© ISO 2017 – All rights reserved

This is a preview of "BS EN ISO 21149:2017...". Click here to purchase the full version from the ANSI store.

Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria

1 Scope

This document gives general guidelines for enumeration and detection of aerobic mesophilic bacteria present in cosmetics

— by counting the colonies on agar medium after aerobic incubation, or

— by checking the absence of bacterial growth after enrichment.

Because of the large variety of cosmetic products within this field of application, this method may not be appropriate for some products in every detail (e.g. certain water immiscible products). Other methods (e.g. automated) may be substituted for the tests presented here provided that their equivalence has been demonstrated or the method has been otherwise shown to be suitable.

If needed, microorganisms enumerated or detected may be identified using suitable identification tests described in the standards given in the Bibliography.

In order to ensure product quality and safety for consumers, it is advisable to perform an appropriate microbiological risk analysis to determine the types of cosmetic products to which this document is applicable. Products considered to present a low microbiological risk (see ISO 29621) include those with low water activity, hydro-alcoholic products, extreme pH values, etc.

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 21148:2017, *Cosmetics — Microbiology — General instructions for microbiological examination*

EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
aerobic mesophilic bacterium
mesophilic bacterium growing aerobically under the conditions specified in this document

Note 1 to entry: In the described conditions, other types of microorganisms (e.g. yeast, mould) can be detected.

© ISO 2017 – All rights reserved