

SVENSK STANDARD

SS-EN ISO 21148:2017

Fastställt/Approved: 2017-07-19
Publicerad/Published: 2017-07-21
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 07.100.40; 07.100.99; 71.100.70

Kosmetika – Mikrobiologi – Generella instruktioner för mikrobiologisk undersökning (ISO 21148:2017)

Cosmetics – Microbiology – General instructions for microbiological examination (ISO 21148:2017)

This preview is downloaded from www.sis.se. Buy the entire standard via <https://www.sis.se/std-8027480>

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka

Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet

Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standardpaket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete

Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.



Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence

As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work

We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception

With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00



Europastandarden EN ISO 21148:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 21148:2017.

Denna standard ersätter SS-EN ISO 21148:2009, utgåva 1.

The European Standard EN ISO 21148:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 21148:2017.

This standard supersedes the Swedish Standard SS-EN ISO 21148:2009, edition 1.

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Kosmetik samt analysmetoder för allergener, SIS/TK 495.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 21148

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2017

ICS 07.100.99; 71.100.70

Supersedes EN ISO 21148:2009

English Version

Cosmetics - Microbiology - General instructions for microbiological examination (ISO 21148:2017)

Cosmétiques - Microbiologie - Instructions générales
pour les examens microbiologiques (ISO 21148:2017)

Kosmetische Mittel - Mikrobiologie - Allgemeine
Anleitungen zur mikrobiologischen Untersuchung (ISO
21148:2017)

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

Contents

Page

European foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Premises	1
4.1 Test areas	1
4.2 Additional areas	2
4.3 Location of the premises	2
4.4 Equipping the premises	2
4.5 Maintenance	3
5 Equipment	3
5.1 General	3
5.2 Microbiological cabinets	3
5.3 Balances	3
5.4 Homogenizer	4
5.5 pH-meter	4
5.6 Autoclave	4
5.7 Incubator	4
5.8 Water baths	4
5.9 Refrigerator or cold-storage room	4
5.10 Freezer	4
5.11 Sterilizing oven	5
5.12 Colony-counting device	5
5.13 Other equipment	5
6 Strains of microorganisms	5
7 Personnel	6
7.1 Competence	6
7.2 Hygiene	6
8 Preparation of the apparatus and glassware	6
8.1 Preparation	6
8.2 Sterilization	6
8.2.1 Sterilization by dry heat	6
8.2.2 Sterilization by moist heat	7
8.3 Disposable apparatus	7
8.4 Management of clean apparatus and glassware	7
8.5 Management of sterile apparatus and glassware	7
8.6 Treatment of contaminated material	7
8.7 Washing	7
9 Preparation and sterilization of culture media and reagents	8
9.1 General	8
9.2 Water	8
9.3 Preparation of culture media	8
9.3.1 General	8
9.3.2 Rehydration	8
9.3.3 Measurement of pH	8
9.3.4 Dispensing	8
9.4 Sterilization	9
9.4.1 General	9
9.4.2 Sterilization by moist heat	9
9.4.3 Sterilization by filtration	9

SS-EN ISO 21148:2017 (E)

9.5	Storage	9
9.5.1	General	9
9.5.2	Laboratory-prepared culture media and reagents	9
9.5.3	Ready-to-use culture media and reagents	10
9.6	Melting of agar culture media	10
9.7	Preparation of Petri dishes	10
10	Laboratory samples	10
10.1	General	10
10.2	Sampling the cosmetic product	10
10.3	Transport	10
10.4	Receipt and storage	11
10.5	Handling products and samples	11
10.6	Conservation and destruction of products	11
11	Operating practices	11
11.1	Hygienic precautions during the testing	11
11.2	Preparation of the initial suspension and of sample dilutions	12
11.2.1	General	12
11.2.2	Water-miscible product	12
11.2.3	Water-immiscible products	13
11.3	Counting methods	13
11.4	Detection methods	13
12	Expression of results	13
13	Neutralization of the antimicrobial properties of the product	13
Annex A (informative) Basic identification techniques		14
Annex B (informative) Basic techniques for counting and plating		19
Annex C (informative) Preparation and calibration of inoculums		20
Bibliography		21

European foreword

This document (EN ISO 21148:2017) 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 21148:2009.

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 21148:2017 has been approved by CEN as EN ISO 21148:2017 without any modification.

SS-EN ISO 21148:2017 (E)

Introduction

The purpose of this document is to help ensure that the general techniques used for conducting cosmetic microbiological examinations are the same in other laboratories that adopt these standards, to help achieve homogeneous results in different laboratories and to contribute towards the protection of the health of the laboratory personnel by preventing risk of infection.

When conducting microbiological examinations for cosmetic products, it is especially important that:

- only those microorganisms which are present in the samples be isolated or enumerated;
- the microorganisms do not contaminate the environment.

In order to achieve this, it is necessary to pay attention to personal hygiene and to use working techniques which ensure, as far as possible, exclusion of extraneous contamination.

Since, in this document, it is possible to give only a few examples of the precautions to be taken during microbiological examinations, a thorough knowledge of the microbiological techniques and of the microorganisms involved is essential. It is important that the analyses be conducted as accurately as possible, including calculation of the number of microorganisms.

A large number of manipulations can, for example, unintentionally lead to cross-contamination and the analyst should always verify the accuracy of the results given by his/her technique. It is necessary to take special precautions, not only for reasons of hygiene, but also to ensure good reproducibility of the results. It is not possible to specify all the precautions to be taken in all circumstances, but this document at least provides the main measures to be taken when preparing, sterilizing and storing the media and the equipment.

The given recommendations will allow enumeration and detection of mesophilic microorganisms which may grow under aerobic conditions.

The recommendations are applicable to the determination of the absence of, or limited occurrence of specified microorganisms that are of interest for cosmetic products.

The test methods are described in the individual standards. Alternative microbiological procedures can be used provided that their equivalence has been demonstrated or the method has been otherwise demonstrated to be suitable. The choice of a specific method, or combination of methods mentioned in these International Standards will depend on the purpose for performing the test and it is for the user to decide which approach is best for his/her application.

Cosmetics — Microbiology — General instructions for microbiological examination

1 Scope

This document gives general instructions for carrying out microbiological examinations of cosmetic products, in order to ensure their quality and safety, in accordance with an appropriate risk analysis (e.g. low water activity, hydro-alcoholic, extreme pH values).

Because of the large variety of products and potential uses within this field of application, these instructions might not be appropriate for some products in every detail (e.g. certain water-immiscible products).

2 Normative references

There are no normative references in this document.

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

product

portion of an identified cosmetic product received in the laboratory for testing

3.2

sample

portion of the *product* (3.1) (at least 1 g or 1 ml) that is used in the test to prepare the *initial suspension* (3.3)

3.3

initial suspension

suspension (or solution) of the *sample* (3.2) in a defined volume of an appropriate enrichment broth

3.4

sample dilution

dilution of the *initial suspension* (3.3)

4 Premises

4.1 Test areas

The areas required for the specific operation of a microbiology laboratory are as follows:

- receipt, storage, preparation and processing of the samples;
- preparation and sterilization of culture media, apparatus and glassware;