
Kozmetika - Analizne metode - Določevanje težkih kovin v sledovih v končnih kozmetičnih izdelkih z masno spektrometrijo z induktivno sklopljeno plazmo (ICP/MS) (ISO 21392:2021)

Cosmetics - Analytical methods - Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique (ISO 21392:2021)

Kosmetische Mittel - Untersuchungsverfahren - Messung von Spuren von Schwermetallen in fertigen kosmetischen Mitteln mittels ICP-MS (ISO 21392:2021)

Cosmétiques - Méthodes d'analyse - Mesurage des éléments traces métalliques par ICP-MS dans les produits cosmétiques finis (ISO 21392:2021)

<https://standards.iteh.ai/catalog/standards/sist/4b416b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

Ta slovenski standard je istoveten z: EN ISO 21392:2021

ICS:

71.100.70

Kozmetika. Toaletni
pripomočki

Cosmetics. Toiletries

SIST EN ISO 21392:2022

en,fr,de

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 21392

September 2021

ICS 71.100.70

English Version

Cosmetics - Analytical methods - Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique (ISO 21392:2021)

Cosmétiques - Méthodes d'analyse - Mesurage des éléments traces métalliques par ICP-MS dans les produits cosmétiques finis (ISO 21392:2021)

Kosmetische Mittel - Untersuchungsverfahren - Messung von Spuren von Schwermetallen in fertigen kosmetischen Mitteln mittels ICP-MS (ISO 21392:2021)

This European Standard was approved by CEN on 2 August 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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21392:2022
<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

European foreword

This document (EN ISO 21392:2021) 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 March 2022, and conflicting national standards shall be withdrawn at the latest by March 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.

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

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 websites.

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.

SIST EN ISO 21392:2022

<https://standards.iteh.ai/en/standards/EN-ISO-21392-2022/6-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

Endorsement notice

The text of ISO 21392:2021 has been approved by CEN as EN ISO 21392:2021 without any modification.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

INTERNATIONAL STANDARD

ISO
21392

First edition
2021-08

Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique

*Cosmétiques — Méthodes d'analyse — Mesurage des éléments traces
métalliques par ICP-MS dans les produits cosmétiques finis*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>



Reference number
ISO 21392:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	1
5 Reagents	2
6 Apparatus and equipment	2
7 Preparation of standards solutions	3
7.1 General	3
7.2 Diluted nitric acid	3
7.3 Diluting solution	4
7.4 Internal standard solutions	4
7.4.1 General	4
7.4.2 Rhodium standard solution, 1 mg/l	4
7.4.3 Lutetium standard solution, 1 mg/l	4
7.5 Standard solutions	4
7.5.1 General	4
7.5.2 High concentration mixed standard solution, 10 mg/l	5
7.5.3 Low concentration mixed standard solution, 0,1 mg/l	5
7.6 Calibration blank solution	5
7.7 Calibration solutions	5
8 Procedure	6
8.1 Preparation of samples	6
8.2 Pressure assisted digestion	6
8.2.1 General	6
8.2.2 Preparation of sample by digestion — General case	6
8.2.3 Preparation of sample by digestion — Specific cases	7
8.2.4 Microwave digestion procedure	7
8.2.5 Preparation of measurement solutions	8
8.3 Inductively coupled plasma mass spectrometry	8
8.3.1 ICP-MS operating conditions	8
8.3.2 Quantification of the analytes by ICP-MS	8
8.4 Quality control of the analysis	9
8.4.1 General	9
8.4.2 During digestion	10
8.4.3 During analysis	11
8.4.4 Example of ICP-MS sequence	11
9 Calculation	12
10 Method performance	12
11 Test report	13
Annex A (informative) Performance of the method determined by the accuracy profile methodology	14
Annex B (informative) Evaluation of the method via ISO 5725 statistical approach	22
Bibliography	30

ISO 21392:2021(E)

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 392, *Cosmetics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

This document specifies an analytical procedure for the determination of trace levels of heavy metals (e.g. chromium, cobalt, nickel, arsenic, cadmium, antimony and lead) in finished cosmetic products by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion of the sample. This type of analytical procedure is widely described in other areas such as environment [9][10][11], food [9][10][11] and pharmaceutical industry [12][13][14][15]. While it maximizes the detection of trace levels present in cosmetic products, it does not provide any methodology to directly evaluate systemic exposure of the consumers.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 21392:2022

<https://standards.iteh.ai/catalog/standards/sist/f4b4f6b3-7106-49bf-bfa0-90725be532eb/sist-en-iso-21392-2022>

Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique

1 Scope

This document provides a method for quantification of trace levels of heavy metals in cosmetic products.

This document refers only to chromium, cobalt, nickel, arsenic, cadmium, antimony and lead. The methodology can apply to other elements, however, it is the responsibility of the analyst to demonstrate that it fits that purpose.

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 3696, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions (standards.iteh.ai)

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:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

validation range

range from the upper to the lower concentration of samples used for the method evaluation

3.2

validated range

range of concentrations between the upper and lower levels that the method performance has been demonstrated to be compliant with the method requirements

4 Principle

Trace levels of heavy metals in cosmetic products are quantified by ICP-MS measurement of the solutions following digestion of the cosmetic products. Digestion takes place with mineral acids in sealed vessels heated to 200 °C by microwaves, producing high pressures.

In the sample preparation procedure, cosmetic ingredients are digested by using a nitric acid/hydrochloric acid mixture allowing the trace levels of heavy metal to be solubilized for measurement. It is possible that some cosmetic inorganic ingredients, such as silica or titanium dioxide, are not completely digested under the conditions of this document and that heavy metal confined in such ingredients are not fully extracted. However, the level of heavy metal trapped in these inorganic materials is not considered to significantly contribute to the exposure level of consumers to these heavy metals. The use of ICP-MS ensures reliable measurement of trace levels of heavy metals due to its proven high sensitivity and selectivity.