

Cosmetics - Analytical methods - Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique (ISO 21392:2021, Corrected version 2021-12)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

|   |  |
|---|--|
| See Eesti standard EVS-EN ISO 21392:2021 sisaldab Euroopa standardi EN ISO 21392:2021 ingliskeelset teksti.         | This Estonian standard EVS-EN ISO 21392:2021 consists of the English text of the European standard EN ISO 21392:2021.                                |
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| Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.09.2021. | Date of Availability of the European standard is 01.09.2021.   |
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English Version

**Cosmetics - Analytical methods - Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique (ISO 21392:2021, Corrected version 2021-12)**

Cosmétiques - Méthodes d'analyse - Mesurage des éléments traces métalliques par ICP-MS dans les produits cosmétiques finis (ISO 21392:2021, Version corrigée 2021-12)

Kosmetische Mittel - Untersuchungsverfahren - Messung von Spuren von Schwermetallen in fertigen kosmetischen Mitteln mittels ICP-MS (ISO 21392:2021, korrigierte Fassung 2021-12)

This European Standard was approved by CEN on 2 August 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 22 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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

## 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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.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.

## Endorsement notice

The text of ISO 21392:2021, Corrected version 2021-12 has been approved by CEN as EN ISO 21392:2021 without any modification.

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## 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](http://www.iso.org/directives)).

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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](http://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](http://www.iso.org/members.html).

This corrected version of ISO 21392:2021 incorporates the following corrections:

- the definition of [Formula \(1\)](#) has been corrected.

## 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.

# 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

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.