

SVENSK STANDARD

SS-EN ISO 21392:2021

Kosmetik – Analytiska metoder – Mätning av spår av tungmetaller i färdiga kosmetiska produkter med ICP / MS-teknik (ISO 21392:2021)

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



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Europastandarden EN ISO 21392:2021 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 21392:2021.

The European Standard EN ISO 21392:2021 has the status of a Swedish Standard. This document contains the official version of EN ISO 21392:2021.

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Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

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A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary **shall** (or **shall not** for prohibition).

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A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary **should** (or **should not** for dissuasion).

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An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

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EUROPEAN STANDARD

EN ISO 21392

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 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)**

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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

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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).

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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.

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.

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.

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Endorsement notice

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

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.

In order to obtain comparable results, it is absolutely mandatory to follow all the conditions linked to the digestion of the samples.