SLOVENSKI STANDARD
SIST ISO 15819:2015

01-marec-2015

Nadomešča:
SIST ISO 15819:2009

Kozmetika - Analizne metode - Nitrozamini: odkrivanje in določevanje N-nitrozodietanolamina (NDELA) v kozmetičnih izdelkih s tekočinsko kromatografijo visoke ločljivosti z masno spektrometrijsko detekcijo (HPLC-MS-MS)

Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS

Cosmétiques - Méthodes analytiques - Nitrosamines: Recherche et dosage de la N-nitrosodiéthanolamine (NDELA) dans les produits cosmétiques par CLHP-SM-SM

Ta slovenski standard je istoveten z: **ISO 15819:2014**

ICS:

71.040.50	Fizikalnokemijske analitske metode	Physicochemical methods of analysis
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

SIST ISO 15819:2015 **en**

INTERNATIONAL STANDARD

ISO 15819

Second edition
2014-10-15

Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS

Cosmétiques — Méthodes analytiques — Nitrosamines: Recherche et dosage de la N-nitrosodiéthanolamine (NDELA) dans les produits cosmétiques par CLHP-SM-SM

Reference number
ISO 15819:2014(E)

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Published in Switzerland

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 15819:2008), which has been technically revised.

Introduction

Human exposure to N-nitrosamines can occur through diverse sources such as environment, food, or personal care products. As a result of their perceived carcinogenic potential on several animal species, minimization of exposure to N-nitrosamines is recognized as important to the preservation of human health. Among N-nitrosamines, N-nitrosodiethanolamine (NDELA) has been recognized as a potential contaminant of cosmetics.

In this context, several analytical methods have been developed to detect and determine its presence in cosmetics, such as gas chromatography/thermal energy analysis, high performance liquid chromatography (HPLC) coupled either with photolysis and colourimetric quantification or with mass spectrometry (MS) determination. This latter method uses advanced technology to ensure the maximum specificity towards NDELA, to minimize the risk of artefactual formation of the analyte of interest and to allow precise quantification.

This analytical method uses high performance liquid chromatography coupled with mass spectrometry to separate and detect trace levels of NDELA from a cosmetic ingredient or product matrix with maximum specificity for NDELA.

Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS

1 Scope

This International Standard describes a method for the detection and quantification of N-nitrosodiethanolamine (NDELA) in cosmetics and raw materials used in cosmetics.

This method is not applicable to the detection and/or quantification of nitrosamines other than NDELA nor to the detection and/or quantification of NDELA in products other than cosmetics or raw materials used in cosmetics.

If a product has a possibility of either NDELA contamination from ingredients or NDELA formation by the composition of ingredients, the method is intended to be applied for quantitative determination of NDELA. Accordingly, the method does not apply to routine testing of cosmetic products. Because of the large variety of cosmetic products within this field of application, this method might need to be adapted for certain matrices (refer to ISO 12787).

Therefore, International Standards dedicated to alternative methods for testing nitrosamines in cosmetic products are being developed separately. Other methods can be employed provided that they are verified as to their detection of NDELA and validated in terms of recovery and quantification of the analyte.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 12787:2011, *Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques*

3 Principle

Extraction of NDELA in cosmetics samples is carried out with water in the presence of deuterated d8-NDELA used as internal standard (IS). Clean-up is performed either using solid phase extraction (SPE clean-up, see 6.3.1) with a C18 cartridge or liquid–liquid extraction using dichloromethane (DCM clean-up, see 6.3.2) when the samples are not dispersible in water. The extracts are analysed by HPLC-MS-MS (high performance liquid chromatography coupled with tandem mass spectrometric detection).

Identification of NDELA is carried out by using the molecular ion and two diagnostic ions. NDELA quantification is done by comparing the ratio of the major fragment ions of NDELA and d8-NDELA with the calibration curve.

In accordance with the ISO 12787, the absence of NDELA in the sample could be confirmed with a second analysis. A spiked preparation at a target value could be performed to evaluate the limit of detection of NDELA in the sample.

If matrix effect is observed with significant impact on the performance of the method (sensitivity, accuracy, etc.) for specific cosmetic product, standard addition calibration procedures could be utilized (refer to ISO 12787).

