

**SINGAPORE STANDARD**

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

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

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## **National Foreword**

This Singapore Standard was prepared by the National Mirror Working Group on Cosmetics under the direction of the Biomedical Standards Committee. This Singapore Standard is an identical adoption of International Standard ISO 15819:2014 “Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS” published by the International Organization for Standardization.

Attention is drawn to the following:

1. Where appropriate, the words ‘International Standard’ shall be read as ‘Singapore Standard’. The reference to ‘ISO 12787’ shall be replaced by ‘SS ISO 12787’
2. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

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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](http://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*