Method for Analysis of Allergens - Quantification of an extended list of 57 suspected allergens in ready to inject fragrance materials by gas chromatography mass spectrometry

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 16274:2021 sisaldab Euroopa standardi EN 16274:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 16274:2021 consists of the English text of the European standard EN 16274:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 05.05.2021.	Date of Availability of the European standard is 05.05.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 71.100.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16274

May 2021

ICS 71.100.60

Supersedes EN 16274:2012

English Version

Method for analysis of allergens - Quantification of an extended list of 57 suspected allergens in ready to inject fragrance materials by gas chromatography mass spectrometry

Méthode d'analyse des allergènes - Quantification de la liste étendue des 57 allergènes suspectés dans les matières premières de parfumerie et les compositions parfumantes prêtes à être injectées, par chromatographie en phase gazeuse/spectrométrie de masse

Analyseverfahren für Allergene - Quantifizierung einer erweiterten Liste von 57 zu vermutenden Allergenen in einspritzfertigen Duftstoffen mittels Gaschromatographie/Massenspektrometrie

This European Standard was approved by CEN on 8 February 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

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Ref. No. EN 16274:2021 E

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European foreword

This document (EN 16274:2021) has been prepared by Technical Committee CEN/TC 347 “Methods for analysis of allergens”, the secretariat of which is held by SNV.

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 November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

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 supersedes EN 16274:2012.

The most significant technical changes made in comparison to the previous version are as follows:

— Number of allergens has been extended from 26 to 57 chemically defined molecules.

— Solvents: moves from methyl pivalate and ortho fluorotoluene and acetone to methyl pivalate and MTBE and other solvents provided they are tested prior being used.

— Sample preparation: allows to use weight/volume approach rather than only weight/weight.

— Data processing: provides explanations for a calibration curve using a forced through zero approach.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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.

Introduction

Directive 2003/15/EC amending Council Directive 76/768/EEC, relating to cosmetic products, regulates the obligation to inform consumers of the presence of 24 chemically-defined fragrance substances identified as potential allergens in cosmetic products. Following the publication of the Scientific Committee on Consumer Safety's document (SCCS/1459/11), it was proposed to extend that to 57 fragrance substances, some of them existing under several isomeric forms or as mixtures. This required the development of a new quantification method in response to the evolution of regulatory requirements.

The new analytical method has been developed using gas chromatography and mass spectrometry (GC-MS), to detect and to quantify the 57 fragrance substances and their relevant isomers in ready to inject fragrance compounds and fragrance raw materials.

The method described in this document does not include requirements for the preparation of samples in matrices for which direct injection in GC is not feasible.

The present document describes a working analytical method based on IFRA Analytical Working Group developments. The analytical method was validated based on a ring test performed by the CEN working group using the accuracy profile approach.

1 Scope

The present method permits the identification and quantification of the volatile compounds suspected as allergens, which are present in the fragrance compounds and fragrance raw materials used in cosmetic products. The analysis is performed by gas chromatography and mass spectrometry (GC-MS) on matrix samples which are “ready to be injected” and which are compatible with gas chromatography.

The analytes covered by this procedure are based on the contents of Tables 13.1 and 13.2 in the SCCS 1459/11 opinion document (1) and as listed in the legislation proposed by the European Commission. The rationale behind the final choice of procedure analytes is given in the table found in Annex J.

The method was validated at IFRA and CEN level.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

4 Principle

This procedure has a calibration range between 2 ppm and 240 ppm, this permits the quantification of suspected allergens in diluted matrices in the range 20 ppm to 2 400 ppm per analyte. Beyond the upper concentration level the recommendation is that the sample should be diluted further, or that GC-FID (GC with Flame Ionization Detection) is used preferably in combination with internal standard and response factors.

The matrix samples are analysed for suspected allergens by GC-MS in a total of 4 runs, using 2 analyte sets, both injected on two separate columns of differing polarity. Where necessary the matrix samples should first be diluted in an appropriate solvent.

Their identification and quantification are achieved by selected ion monitoring (SIM; SIM-SCAN) mode via the relative abundance of 3 characteristic fragment ions. The calculation and use of the corresponding Q value or similar data evaluation factor can be applied and a ‘Decisional Tree’ (see Annex F, Figure F.1) for the final inspection and validation of the data by a trained and experienced analyst is described. An additional full-SCAN analysis is recommended to confirm the presence of the allergen in matrix samples if only SIM methodology was used.

Their quantification is achieved in all modes by calibration using standard solutions and the internal standards 1,4-dibromobenzene and 4,4’-dibromobiphenyl. The ‘Decisional Tree’ is employed to determine the final concentration taking into account the different concentration values obtained from analysis on both columns.