

<b>STN</b>	<b>Metóda analýzy alergénov Kvantifikácia rozšíreného zoznamu 57 potenciálnych alergénov priamou analýzou vonných látok metódou plynovej chromatografie a hmotnostnej spektrometrie</b>	<b>STN EN 16274</b>  85 5269
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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

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/21

Obsahuje: EN 16274:2021

Oznámením tejto normy sa ruší  
STN EN 16274 (85 5269) z januára 2013

**133449**



EUROPEAN STANDARD

**EN 16274**

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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

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**EN 16274:2021 (E)****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of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.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).

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## **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.

**EN 16274:2021 (E)****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.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**