Methods for analysis of allergens - Quantification of suspected fragrance allergens in consumer products - Step 1: GC analysis of ready-to-inject sample

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NATIONAL FOREWORD

See Eesti standard EVS-EN 16274:2012 sisaldab Euroopa standardi EN 16274:2012 ingliskeelset teksti.	This Estonian standard EVS-EN 16274:2012 consists of the English text of the European standard EN 16274:2012.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.09.2012.	Date of Availability of the European standard is 12.09.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

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Methods for analysis of allergens - Quantification of suspected fragrance allergens in consumer products - Step 1: GC analysis of ready-to-inject sample

Méthodes d'analyse des allergènes - Quantification des fragrances allergènes suspectées dans les produits de consommation - Étape 1 : Analyse par GC d'échantillons prêts à être injectés

Analyseverfahren für Allergene - Quantifizierung von mutmaßlichen Allergie auslösenden Duftstoffen in Verbrauchsgütern - Stufe 1: GC-Analyse von einspritzfertigen Proben

This European Standard was approved by CEN on 4 August 2012.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 16274:2012) has been prepared by Technical Committee CEN/TC 347 “Methods for analysis of allergens”, the secretariat of which is held by DS.

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of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Introduction

Human skin exposure to suspected allergenic fragrances can occur through diverse sources such as detergents and cosmetics intended to be rinsed or not. As a result of their possible effect, 26 fragrance substances have been restricted under Council Directives with labelling requirements in order to insure a high level of protection of consumers, particularly for sensitive population.

In this context, several analytical methods have been developed to detect and determine their presence in cosmetics such as Gas Chromatography/Flame Ionisation Detector (GC-FID), Gas Chromatography/Mass Spectrometry (GC-MS), comprehensive GC or MS-MS in raw materials and finished products.

The present analytical method uses GC-MS by combination of two GC columns of different polarity with a dedicated methodology for quantification [1]. This allows separation and quantification of the 24 volatile suspected allergens above 0,001 % (10 mg/kg) of each, in ready-to-inject sample from a cosmetic ingredient or product matrix. The present protocol has been validated thanks to a ring test [2].

1 Scope

This European Standard describes a method for the identification and determination of 24 volatile suspected allergens from ready-to-inject cosmetics and raw materials used in cosmetic products and are compatible with GC analysis. This analysis uses GC-MS after sample preparation. The 24 suspected allergens are restricted under Council Directives (7th amendment to the Cosmetic Directive 2003/15/EC).

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

2 Principle

The method described in this European Standard is a comprehensive analysis of 24 volatile suspected allergens by Gas Chromatography coupled with Mass Spectrometry after dilution of the sample in an inert solvent.

Two assays are performed for the chromatographic separation of the 24 suspected allergens using two GC capillary columns of different polarities. Suspected allergen identification is achieved when possible using GC-MS in scan mode. Quantification is performed by single ion monitoring (SIM) using 1,4-dibromobenzene and 4,4'-dibromobiphenyl as internal standards.

The final result depends on the agreement of the different ion ratios obtained for both injections according to specific requirements.

3 Reagents

Unless otherwise stated, use only reagents of recognised analytical grade. The solvent shall be of quality for GC-MS analysis.

3.1 Solvents

3.1.1 Methyl pivalate, CAS no: [598-98-1], analytical grade or higher.

3.1.2 Ortho-fluorotoluene, CAS no: [95-52-3], analytical grade or higher.

3.1.3 Acetone, CAS no: [67-64-1], analytical grade or higher.

IMPORTANT — if other solvents are used, their inertness with the analytes shall be demonstrated. In any case, the same solvent shall be used both for calibration and determination.

3.2 Fragrance (suspected allergen) standards

3.2.1 Amylcinnamic alcohol, CAS no: [101-85-9], with known purity.

NOTE Possibly two isomers.

3.2.2 Amylcinnamic aldehyde (flosal®), CAS no: [122-40-7], with known purity.

NOTE Possibly two isomers.

3.2.3 Anisyl alcohol, CAS no: [105-13-5], with known purity.

3.2.4 Benzyl alcohol, CAS no: [100-51-6], with known purity.

3.2.5 Benzyl benzoate, CAS no: [120-51-4], with known purity.