

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

EESTI STANDARDI EESSÕNA

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English Version

**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.

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of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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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.