



**NSAI**  
Standards

Irish Standard  
I.S. EN ISO 16186:2021

Footwear - Critical substances potentially present in footwear and footwear components - Determination of dimethyl fumarat (DMFU) (ISO 16186:2021)

**I.S. EN ISO 16186:2021**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN ISO 16186:2021

*Published:*

2021-06-16

*This document was published under the authority of the NSAI and comes into effect on:*

2021-07-05

ICS number:

61.060

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

I.S. EN ISO 16186:2021 is the adopted Irish version of the European Document EN ISO 16186:2021, Footwear - Critical substances potentially present in footwear and footwear components - Determination of dimethyl fumarat (DMFU) (ISO 16186:2021)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

EUROPEAN STANDARD

EN ISO 16186

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2021

ICS 61.060

Supersedes CEN ISO/TS 16186:2012

English Version

## Footwear - Critical substances potentially present in footwear and footwear components - Determination of dimethyl fumarat (DMFU) (ISO 16186:2021)

Chaussures - Substances critiques potentiellement présentes dans les chaussures et les composants de chaussures - Détermination du diméthylformamide (DMF) (ISO 16186:2021)

Schuhe - Möglicherweise in Schuhen und Schuhbestandteilen vorhandene kritische Substanzen - Bestimmung von Dimethylfumarat (DMFU) in Schuhwerkstoffen (ISO 16186:2021)

This European Standard was approved by CEN on 17 May 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

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

**EN ISO 16186:2021 (E)**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## **European foreword**

This document (EN ISO 16186:2021) has been prepared by Technical Committee ISO/TC 216 "Footwear" in collaboration with Technical Committee CEN/TC 309 "Footwear" the secretariat of which is held by UNE.

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 December 2021, and conflicting national standards shall be withdrawn at the latest by December 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 CEN ISO/TS 16186:2012.

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

## **Endorsement notice**

The text of ISO 16186:2021 has been approved by CEN as EN ISO 16186:2021 without any modification.

This page is intentionally left blank



# INTERNATIONAL STANDARD

ISO  
16186

First edition  
2021-05

---

---

## Footwear — Critical substances potentially present in footwear and footwear components — Determination of dimethyl fumarate (DMFU)

*Chaussures — Substances critiques potentiellement présentes dans  
les chaussures et les composants de chaussures — Détermination du  
fumarate de diméthyle (DMFU)*



Reference number  
ISO 16186:2021(E)

© ISO 2021

**ISO 16186:2021(E)**



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Principle</b> .....	<b>1</b>
<b>5 Reagents and materials</b> .....	<b>2</b>
<b>6 Apparatus</b> .....	<b>2</b>
<b>7 Sampling</b> .....	<b>3</b>
<b>8 Procedure</b> .....	<b>3</b>
8.1 Standard procedure.....	3
8.2 Procedure for complex matrix.....	3
8.2.1 Extraction.....	3
8.2.2 Clean-up.....	4
8.3 Preparation of calibration solutions.....	4
8.4 Determination of dimethyl fumarate.....	4
<b>9 Expression of results</b> .....	<b>4</b>
9.1 Calculation of dimethyl fumarate in the sample.....	4
9.2 Limit of quantification (LOQ).....	5
<b>10 Test report</b> .....	<b>5</b>
<b>Annex A (informative) The chromatography parameters (GC-MS)</b> .....	<b>6</b>
<b>Annex B (informative) The chromatography parameters (GC-MS/MS)</b> .....	<b>8</b>
<b>Annex C (informative) Rationale for excluding methanol as extraction solvent</b> .....	<b>10</b>
<b>Annex D (informative) Reliability of the method</b> .....	<b>11</b>
<b>Bibliography</b> .....	<b>12</b>

## ISO 16186:2021(E)

### Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 216, *Footwear*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 309, *Footwear*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 16186 cancels and replaces ISO/TS 16186:2012, which has been technically revised.

The main changes compared to the previous edition are as follows:

- new [Clause 3](#), [6.6](#), [6.8](#), [6.9](#);
- gas chromatograph with tandem quadrupole mass spectrometer (GC-MS/MS);
- in [Clause 7](#), desiccant treated as a note;
- in [8.2.2](#), new clean up procedure;
- new [Annexes A](#), [B](#) and [C](#);
- Tabled [D.1](#) aligned with [Table D.2](#);
- bibliography added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## **Introduction**

Dimethyl fumarate (DMFU) has been found to be a sensitizer at very low concentrations, producing extensive, pronounced eczema, which is difficult to treat.

There are regulations that limit the use of DMFU. For example in the EU, products, or any parts thereof, containing DMFU in concentrations greater than 0,1 mg/kg are not authorized on the market<sup>[3]</sup>.



# Footwear — Critical substances potentially present in footwear and footwear components — Determination of dimethyl fumarate (DMFU)

**WARNING** — The use of this document can involve hazardous materials, operations and equipment. It does not purport to address all of the safety or environmental problems associated with its use. It is the responsibility of users of this document to take appropriate measures to ensure the safety and health of personnel and the environment prior to application of the document, and to determine the applicability of regulatory limitations for this purpose.

## 1 Scope

This document specifies a method for the determination of the content of dimethyl fumarate (DMFU) by gas chromatograph with single quadrupole mass spectrometer (GC-MS) or tandem quadrupole mass spectrometer (GC-MS/MS).

This document is applicable to all types of footwear and footwear components except metal parts.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4787, *Laboratory glassware — Volumetric instruments — Methods for testing of capacity and for use*

## 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:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

## 4 Principle

The sample is extracted using acetone (see precaution for the solvent in [Annex C](#)) at 60 °C in an ultrasonic bath. At this step, two different procedures can be used, depending on the material being tested:

- a) The “standard procedure,” without purification and concentration of the extracted solution, can be used for samples giving a simple chromatogram, for example, textile footwear components.
- b) The “procedure for complex matrix”, with purification and concentration of the extract, can be used for samples with a complex matrix effect, such as leather.

An aliquot of the extract is analysed using a gas chromatography with single quadrupole mass spectrometry (GC-MS) or tandem quadrupole mass spectrometry (GC-MS/MS).

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-