

STN	Obuv Kritické látky potenciálne prítomné v obuvi a dielcoch obuvi Stanovenie dimetylfumarátu (DMFU) v materiáloch obuvi (ISO 16186: 2021)	STN EN ISO 16186 79 5911
------------	--	--

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

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. 09/21

Obsahuje: EN ISO 16186:2021, ISO 16186:2021

Oznámením tejto normy sa ruší
STN P CEN ISO/TS 16186 (79 5699) z januára 2013

133338

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

Contents	Page
European foreword.....	3

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.

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
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	1
5 Reagents and materials	2
6 Apparatus	2
7 Sampling	3
8 Procedure	3
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
9 Expression of results	4
9.1 Calculation of dimethyl fumarate in the sample.....	4
9.2 Limit of quantification (LOQ).....	5
10 Test report	5
Annex A (informative) The chromatography parameters (GC-MS)	6
Annex B (informative) The chromatography parameters (GC-MS/MS)	8
Annex C (informative) Rationale for excluding methanol as extraction solvent	10
Annex D (informative) Reliability of the method	11
Bibliography	12

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).

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).

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.

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.

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^[3].

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN