
**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)*



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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).

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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/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*

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).