## PD CEN ISO/TR 16178:2012



**BSI Standards Publication** 

# Footwear — Critical substances potentially present in footwear and footwear components (ISO/TR 16178:2012)

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The UK participation in its preparation was entrusted to Technical Committee TCI/69, Footwear, leather and coated fabrics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 76485 1

ICS 61.060

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2012.

#### Amendments issued since publication

Date Text affected

CENICOTO ACATO

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### **TECHNISCHER BERICHT**

September 2012

ICS 61.060

Supersedes CEN ISO/TR 16178:2010

**English Version** 

# Footwear - Critical substances potentially present in footwear and footwear components (ISO/TR 16178:2012)

Chaussures - Substances critiques potentiellement présentes dans la chaussure et les composants de chaussures (ISO/TR 16178:2012) Schuhe - Möglicherweise in Schuhen und Schuhbestandteilen vorhandene kritische Substanzen (ISO/TR 16178:2012)

This Technical Report was approved by CEN on 30 July 2012. It has been drawn up by the Technical Committee CEN/TC 309.

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Ref. No. CEN ISO/TR 16178:2012: E

### Foreword

This document (CEN ISO/TR 16178:2012) has been prepared by Technical Committee CEN/TC 309 "Footwear", the secretariat of which is held by AENOR, in collaboration with Technical Committee ISO/TC 216 "Footwear".

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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#### 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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ISO/TR 16178 was prepared by Technical Committee ISO/TC 216, Footwear.

ISO/TR 16178 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 309, *Footwear*, in collaboration with ISO Technical Committee TC 216, *Footwear*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna agreement).

This second edition cancels and replaces the first edition (ISO/TR 16178:2010), which has been technically revised.

# Footwear — Critical substances potentially present in footwear and footwear components

#### 1 Scope

This Technical Report establishes a list of critical chemical substances potentially present in footwear and footwear components.

This Technical Report describes the critical chemical substances, their potential risks, the materials in which they can be found and the test method(s) which can be used to quantify them. It does not include requirements; it is the responsibility of the user of this Technical Report to fix his/her level of acceptance, for instance using a defined concentration or detection limit or quantification limit.

NOTE The proposed test methods indicate the state of the art. Some substances do not include a test method, as no test method is available at the time of publication of this Technical Report. If possible, it is intended to include a test method in a revision of this Technical Report.

This Technical Report applies to any kind of footwear and footwear components.

#### 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 2.1

#### allergen

substance that is capable of inducing an allergic reaction

#### 2.2

#### allergy

immunologically mediated response to certain specific substances

NOTE 1 The specific substances are allergens.

NOTE 2 Type-1 allergy (respiratory allergy) is mediated by IgE antibodies and can cause asthma, rhinitis and urticaria.

NOTE 3 Type-4 allergy (dermal allergy) is mediated by T-cells and can cause dermatitis.

#### 2.3

#### detection limit

value from which a substance is considered detectable

NOTE This means that the signal associated to the substance is three times bigger than the background noise signal. The limit of detection is determined experimentally by the laboratory for each substance.

#### 2.4

#### quantification limit

value from which a substance is considered measurable

NOTE It is the value where the uncertainty of measurement is equal to 50 % of the determined value.

#### 2.5

#### absence of a chemical

state in which a chemical is lacking from a material, where the test method is unable to detect it

NOTE The amount of the chemical is smaller than the detection limit of the test method.