



# SLOVENSKI STANDARD

## SIST-TP CEN ISO/TR 16178:2012

01-november-2012

Nadomešča:

kSIST-TP FprCEN ISO/TR 16178:2010

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**Obuvala - Nevarne snovi, ki so lahko prisotne v obuvalih in njihovih sestavnih delih (ISO/TR 16178:2012)**

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

Schuhe - Möglicherweise in Schuhen und Schuhbestandteilen vorhandene kritische Substanzen (ISO/TR 16178:2012)

Chaussures - Substances critiques potentiellement présentes dans la chaussure et les composants de chaussures (ISO/TR 16178:2012)

**Ta slovenski standard je istoveten z: CEN ISO/TR 16178:2012**

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**ICS:**

61.060      Obuvala      Footwear

**SIST-TP CEN ISO/TR 16178:2012      en,fr**

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TECHNICAL REPORT  
RAPPORT TECHNIQUE  
TECHNISCHER BERICHT

**CEN ISO/TR 16178**

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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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## 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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# TECHNICAL REPORT

# ISO/TR 16178

Second edition  
2012-07-15

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

*Chaussures — Substances critiques potentiellement présentes dans la  
chaussure et les composants de chaussures*

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## ISO/TR 16178:2012(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.

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.

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.

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.

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# 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.

## ISO/TR 16178:2012(E)

**2.6**  
**critical substance**  
 chemical substance that can be found in footwear or footwear components and that can have an effect on the wearer and/or environmental impact due to its chemical reactivity

NOTE 1 The effects caused by critical substances vary. They can be carcinogenic or mutagenic effects, allergy, reaction to toxics, etc.

NOTE 2 Legislations can change; this Technical Report gives the information available at the time of publication. It is the responsibility of the user of this Technical Report to ensure that no changes have occurred.

**2.6.1**  
**critical substances category 1**  
 substances with proven dangerous effect on the wearer

NOTE These substances are restricted by regulation at European level.

**2.6.2**  
**critical substances category 2**  
 substances with dangerous effect on the wearer

NOTE These substances are restricted by regulation at national level in some countries.

**2.6.3**  
**critical substances category 3**  
 substances with environmental impact

NOTE These substances are mentioned in European Ecolabel.

**2.6.4**  
**critical substances category 4**  
 substances that are highly suspected to have an effect on the wearer

NOTE Possibly, these substances are not restricted by regulation at the time of publication of this Technical Report.

**2.6.5**  
**critical substances category 5**  
 substances that are suspected to have an effect on the wearer

NOTE Possibly, these substances are not restricted by regulation at the time of publication of this Technical Report.

## 3 Presence of chemicals in footwear materials

A number of chemicals are present in footwear materials. Table 1 gives:

- materials in which they are supposed to be (for information, see Annex A);
- the list of the critical chemicals, (for information, see Annex B);
- test methods which can be used to provoke and quantify them;
- the potential risk associated with and assessed by the use of the critical substances category scale (see 2.6).

For composite materials, the tests should be conducted on the entire component.

EXAMPLE 1 Coated textile (cotton plus PVC coating): the test on PVC and the test on cellulosic natural fibres should be carried out.

EXAMPLE 2 Mixed textile (PES plus cotton): the test on cellulosic natural textile and the test on PES textile should be carried out.



Table 1 (continued)

Substance (see Annex B)	Test method	Leather			Synthetic material								Natural material				Miscellaneous						
		Leather	Coated leather	Leather fibre board	PVC	EVA	Rubber	PU - TPU elasthan	PE-PP	Polyester	Polyamide	Chloride fibre	Polyacrylic	Latex	Cellulosic natural textile	Proteinic natural textile	Wood - cork	Adhesives	Metal hardware	Prints for textile	Cellulosic materials		
Formaldehyde	EN 120 EN 717-3															2						2	
Formaldehyde	ISO 14184-1																						
Extractible (Sb - As - Pb - Cd - Cr - Co - Cu - Ni - Hg - Zn)	ISO 17072-1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Heavy metals  Extractible Footwear for children less than 36 months old (Sb - As - Pb - Cd - Cr - Co - Cu - Ni - Hg - Zn - Ba - Se)	ISO 17072-1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Total content (Sb - As - Pb - Cd - Cr - Co - Cu - Ni - Hg - Zn)	ISO 17072-2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Total content (As - Cd - Pb)	EN 14602:2004	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Mercaptobenzothiazole																							
Extractible latex proteins	EN 455-3													4									
N-ethylphenylamine														4									
Nickel	EN 1811 CR 12471 (with or without EN 12472)																						
																							1
Nitrosamines	EN 12868																						

