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TECHNICAL REPORT

CEN ISO/TR 16178

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English Version

Footwear - Critical substances potentially present in footwear and footwear components - Lists of critical chemical substances (ISO/TR 16178:2021)

Chaussures - Substances critiques potentiellement présentes dans la chaussure et les composants de chaussures - Listes des substances chimiques critiques (ISO/TR 16178:2021)

Schuhe - Möglicherweise in Schuhen und Schuhbestandteilen vorhandene kritische Substanzen (ISO/TR 16178:2021)

This Technical Report was approved by CEN on 26 July 2021. It has been drawn up by the Technical Committee CEN/TC 309.

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (CEN ISO/TR 16178:2021) 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.

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Footwear — Critical substances potentially present in footwear and footwear components — Lists of critical chemical substances

*Chaussures — Substances critiques potentiellement présentes dans la
chaussure et les composants de chaussures — Listes des substances
chimiques critiques*

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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

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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).

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 third edition cancels and replaces the second edition (ISO/TR 16178:2012), which has been technically revised.

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

- new [Table 1](#) including a new system of grading;
- withdrawn substances:
 - proteins in latex, substances destroying ozone layer, polychlorobiphenyls, polychloroprene, vinyl chloride;
- added substances:
 - benzene, bisphenol, NMP, DMAC, phenyl mercury, quinoline, VOC;
- biocides are grouped together (CMK, OIT, OPP, TCMTB);
- Annex A is now in ISO 21061^[67];
- Annex B is now [Clause 5](#);
- bibliography, updated.

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.

Footwear — Critical substances potentially present in footwear and footwear components — Lists of critical chemical substances

1 Scope

This document defines lists of critical chemical substances potentially present in footwear and footwear components.

This document describes the critical chemical substances, their potential risks of nocuousness, in which materials they could be found, and which test method(s) can be used to quantify them.

The test methods listed indicate the state of the art. For some substances, a test method is not available.

This document is applicable to any kind of footwear and footwear components.

2 Normative references

There are no normative references in this document.

3 Terms and definitions (standards.iteh.ai)

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

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/>

3.1

allergen

substance that is capable of inducing an allergic reaction

3.2

allergy

immunologically mediated response to certain specific substances (allergens)

Note 1 to entry: Type-1 allergy (respiratory allergy) is mediated by IgE antibodies, can cause asthma, rhinitis, urticaria. Type-4 allergy (dermal allergy) is mediated by T-cells, can cause dermatitis.

3.3

limit of detection

value from which a substance is considered as detectable

Note 1 to entry: 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.

3.4

critical substances

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

Note 1 to entry: The effects caused by critical substances vary. It can be carcinogenic or mutagenic effects, allergy, reaction to toxics, etc.

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3.4.1

critical substances category 1

substances with proven dangerous effect on the wearer

Note 1 to entry: These substances are widely restricted by national regulation in several countries.

3.4.2

critical substances category 2

substances with dangerous effect on the wearer

Note 1 to entry: These substances are restricted by national regulation in a limited number of countries.

3.4.3

critical substances category 3

substances that are highly suspected to have an effect on the wearer

Note 1 to entry: These substances might not be restricted by regulation at the time of publication but they are frequently requested by the market stakeholders.

3.4.4

critical substances category 4

substances that are suspected to have an effect on the wearer

Note 1 to entry: These substances might not be restricted by regulation. Substances known to have an allergenic effect on the wearer are included in category 4 for reference.

4 Presence of chemicals in footwear materials

A number of chemicals are present in footwear materials. [Table 1](#) lists the following:

- a) in which materials they are supposed to be. The possible materials potentially used in the footwear industry are given in ISO 21061:2021, Annex C.
- b) a list of critical chemicals, (see [Clause 5](#) for information);
- c) test methods that can be used to quantify them (see Bibliography);
- d) the potential risks associated with their use, assessed by the use of the critical substances' category scale
 - 1) stand for "critical substances category 1";
 - 2) stand for "critical substances category 2";
 - 3) stand for "critical substances category 3";
 - 4) stand for "critical substances category 4".

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

EXAMPLE 1 Coated textile (cotton + PVC coating). Test on PVC and test on cellulosic natural fibres should be done.

EXAMPLE 2 Mixed textile (PES + cotton). Test on cellulosic natural textile and test on PES textile should be done.

Table 1 — Critical chemicals potentially present in footwear and footwear components

Substance (see Annex B)	Test method	Leather			Synthetic material										Natural material				Miscellaneous			
		Leather	Coated leather	Leather board	PVC	EVA	Rubber	PU - TPU elastane	PE-T PP	Polyester	Polyamide	Chloride fibre	Polyacrylic	Latex	Cellulosic natu- ral textile	Proteinic natural textile	Wood - cork	Adhesives	Metal hardware	Prints for textile	Cellulose	
Acrylonitrile						4	4											4				
Alkylphenols(OP, NP) and Alkylpheno- lethoxylates, (OPEO, NPEO)	ISO 18218-1 ISO 18218-2	3	3	3																		
Alkylphenols(OP, NP) and Alkylpheno- lethoxylates, (OPEO, NPEO)	ISO 18254-1 ISO 21084								2	2	2	2		2	2					2		
AZO - arylamines	ISO 17234-1	1	1	1																		
When 4-aminoa- zobenzene is sus- pected	ISO 17234-2	1	1	1																		
AZO - arylamines	ISO 14362-1								1	1	1	1		1	1						1	
When 4-aminoa- zobenzene is sus- pected	ISO 14362-3								1	1	1	1		1	1						1	
Benzene									1	1	1	1		1	1			2				
Biocides (TCMTB, OIT, CMK)	ISO 13365-1 and ISO 13365- 2	4	4	4		4			4	4	4	4		4	4		4					4
Biocides (OPP)	ISO 13365-1 and ISO 13365- 2	2	2	2		2			2	2	2	2		2	2		2					2
Biocides (triclosan)	EN 17134	2	2	2		2			2	2	2	2		2	2		2					2
Bisphenol		2	2	2																		
Cadmium	EN 1122		1			1	1	1	1	1	1											1
Chlorinated paraffin's (Short chained [C10-C13])	ISO 18219-1	2	2	2					2	2	2	2		2	2		2					2